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(71) Applicant: SPINAL CONCEPTS, INC. [US/US]; Suite B-160, 8200 Cameron Road, Austin, TX 78754 (US).

(72) Inventors: WAGNER, Erik, J.; 801 Creekside Lane, Allen, TX 75002 (US). HOCHSCHULER, Stephen, H.; 17214 Club Hill Drive, Dallas, TX 75248 (US). RASHBAUM, Ralph, F.; 6935 Spanky Branch, Dallas, TX 75248 (US). DINSDALE, Michael, C.; 1003 North Park, Richardson, TX 75081 (US). GUYER, Richard, D.; 18401 Turnbridge Drive, Dallas, TX 75252 (US).

(74) Agent: MEYERTONS, Eric, B.; Conley, Rose & Tayon, P.C., P.O. Box 3267, Houston, TX 77253-3267 (US).

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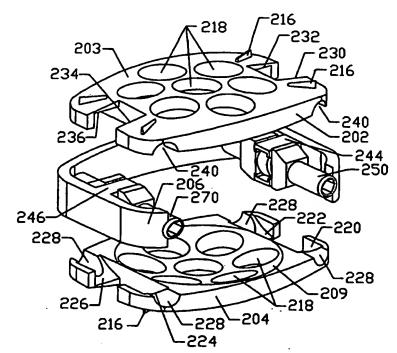
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#### (54) Title: MULTI-VARIABLE HEIGHT FUSION DEVICE

### (57) Abstract

An apparatus (10) promoting a spinal fusion between neighboring vertebrae (16, 18) is disclosed. Apparatus (10) may be located within the intervertebral disc space and preferably includes a pair of engaging plates (12, 14) for contacting the vertebrae (16, 18). An alignment device may be used to alter the vertical height (20) between the engaging plates (12, 14) to customize the apparatus (10) to fit a given patient. In one embodiment, the alignment device includes two turnbuckles (250, 270) and two pairs of cam blocks (260, 261; 280, 281) for adjusting the height between the engaging plates (202, 204). In another embodiment, the alignment device includes three turnbuckles (540, 550, 560) and three pairs of cam blocks (544, 545; 554, 555; 564, 565) for adjusting the height between the engaging plates (502, 504). In another embodiment, the alignment device includes three screws (640, 650, 660) and three cam blocks (644, 654, 664) for adjusting the height between the engaging plates (602, 604). In another embodiment, the alignment device includes four screws and four cam blocks for adjusting the height between the engaging plates. The alignment device may be adapted to vary the height (20) between the engaging plates (12, 14) such that the height of the apparatus (10) proximate the anterior end (22) is greater than that proximate the posterior end (24), whereby the natural lordosis of the spine is maintained after the ap-



paratus (10) is installed, and such that the height (20) of the apparatus (10) proximate the first side edge (26) is substantially different from the height of the apparatus (10) proximate the second side edge (28), whereby the natural lateral alignment of the spine is maintained after the apparatus (10) is installed. In an alternate embodiment, the apparatus includes a single alignment device that may be used to alter the vertical distance between the engaging plates. The alignment device may include a tumbuckle and a single pair of cam blocks for adjusting

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# TITLE: MULTI-VARIABLE-HEIGHT FUSION DEVICE

# **BACKGROUND OF THE INVENTION**

## 1. Field of the Invention

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The present invention generally relates to methods and apparatus for promoting an intervertebral fusion, and more particularly to an apparatus for insertion into a space between adjacent vertebrae to facilitate an intervertebral fusion while maintaining a substantially natural lordosis of the human spine.

# 2. Description of the Related Art

Intervertebral discs that become degenerated due to various factors such as trauma or aging typically have to be partially or fully removed. Removal of an intervertebral disc can destabilize the spine, making it necessary to replace the vertebral disc to maintain the height of the spine and to restore stability. Spinal implants are often used to prevent collapse of the spine and promote fusion. U.S. Serial No. 08/740,123 filed October 24, 1996 relates to methods and apparatus for facilitating a spinal fusion and is incorporated by reference as if fully set forth herein.

After an intervertebral disc is removed, an implant device is typically inserted between neighboring vertebrae to maintain normal disc spacing and restore spinal stability, thereby facilitating an intervertebral fusion. A conventional implant device disposed between neighboring vertebrae is depicted in FIGs. 1 and 2. The implant device contains a pair of engaging elements 20 that typically contain threading 10 to engage the vertebrae. Prior to inserting the engaging elements, a vertebral drill is typically inserted within the surgical wound to drill into the cortical endplate and remove fibrous and nuclear material. A vertebral tap may then be used to cut threads into the ends of the neighboring vertebrae. The engaging elements tend to be relatively inflexible and substantially undeflectable. The engaging elements are typically packed with bone graft to facilitate a spinal fusion.

Conventional implant devices tend to not maintain the "lordosis" or natural curvature of the lower lumbar spine. As shown in FIG. 1, the implant device contains parallel engaging sides 12 and 13 to contact vertebra 15. It is typically required that the engaging sides be parallel to prevent the fusion cage from slipping from the intervertebral space. The parallel configuration of the fusion cage tends to alter the lordosis of the spine. Such a loss of lordosis may result in an increased risk to other intervertebral discs located adjacent to the fusion level that may degenerate due to the altered force transmission in the spine.

FIG. 2 depicts a front view of the engaging elements 20 of the implant device. The engaging elements are substantially cylindrical and the region of contact between an engaging element and a vertebra is defined by arcuate portion 22. The cylindrical geometry of the engaging elements tends to provide a relatively small area of contact between the fusion cage and the vertebrae. The weight of the spine creates pressure on the vertebrae that is concentrated proximate the arcuate portions. Subsidence or deformation of the cortical layer of the vertebrae tends to result.

U.S. Patent No. 5,522,899 to Michelson relates to a spinal implant for placement into the spinal disc space to stabilize the spine and participate in a vertebra to vertebra bony fusion. U.S. Patent No. 5,489,308 to Kuslich et al. relates to an implant for use in spinal stabilization that includes a cylindrical body having

external threading and radially disposed openings positioned to chip bone into an interior portion of the body when the implant is installed. The above-mentioned patents are incorporated by reference as if fully set forth herein.

The above-mentioned prior methods and systems inadequately address, among other things, the need to maintain the natural lordosis of the spine. It is therefore desirable that an improved spinal implant be derived-for facilitating an intervertebral body fusion.

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# SUMMARY OF THE INVENTION

In accordance with the present invention, a spinal implant is provided that largely eliminates or reduces the aforementioned disadvantages of conventional implant devices. An embodiment of the invention relates to a fusion device for facilitating an interbody fusion between neighboring vertebrae of a human spine. The fusion device preferably includes a pair of sides or engaging plates for engaging the vertebrae and an alignment device disposed between the engaging plates for separating the engaging plates to maintain the engaging plates in lordotic alignment. The alignment device is preferably adapted to adjust the height between the engaging plates to customize the fusion device to a particular patient. The height of the fusion device preferably varies along the length of the device such that the height proximate an anterior end of the device differs from the height proximate a posterior end of the device.

The engaging plates are preferably substantially planar so as to inhibit subsidence of the vertebrae. The engaging plates may contain protrusions extending from their outer faces for enhancing an engagement between the vertebra and the engaging plate. The protrusions may be adapted to extend into the vertebra. The engaging plates preferably include a plurality of openings to allow bone growth to occur through the engaging plates. The openings in the face of the engaging plates preferably have a total area that is between about 60 percent and about 80 percent of a total surface area of the face (including the area of the openings).

The fusion device may include a retaining plate proximate the posterior end that serves as a backing against which bone graft may be packed between the engaging plates. The fusion device may also include a removable end cap proximate the anterior end for maintaining bone graft between the engaging plates.

In an embodiment, the alignment device includes a first strut and a second strut that each extend between the engaging plates to define the height therebetween. The fusion device preferably includes a first side and a second side opposite the first side. The first strut preferably runs from the anterior end to the posterior end along a location proximate the first side, and the second strut preferably runs from the anterior end to the posterior end along a location proximate the second side. The engaging plates preferably include a pair of slots sized to receive ends of the struts. The slots may have a substantially dovetail-shaped cross-section that is conformed to the shape of the ends. Each slot is preferably tapered such that its width narrows in a direction from the anterior end to the posterior end whereby the width of the slot proximate the posterior end is less than the width of the end of the strut. The ends of the struts preferably have a lateral width that tapers in substantially the same manner as the slots such that a locking taper engagement is formable between the slots and the ends of the struts.

The height of each strut preferably varies along the length of the strut such that the height between the engaging plates differs between the anterior end and the posterior end to allow the lordosis of the spine to be maintained. The first and second struts may have differing heights to cause the height of the fusion device to vary along the device from the first side to the second side to correct for a lateral deviation in the spinal column. Each of the struts may include a hinge to allow an upper member of the strut to pivot with respect to a lower member of the strut.

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In an alternate embodiment, the engaging plates include slots and the fusion device further includes a pair of pins disposed within the slots. Each engaging plate preferably includes a rib extending in a substantially perpendicular direction from its face. The slot for receiving the pins is preferably disposed on the rib. The pins are preferably substantially elongated and may extend in a direction from the first side to the second side. The fusion device preferably further includes a rotatable connector engaging the pins. Rotation of the connector preferably causes movement of the pins relative to one another to alter the height of the fusion device to create a desired lordotic alignment.

The connector is preferably adapted to move axially between the engaging plates and may contain a retaining ring for contacting an engaging plate to limit movement of the connector through the fusion device. The connector preferably moves axially between the engaging plates in a direction from the anterior end to the posterior end, thereby moving the first pin toward the anterior end and the second pin toward the posterior end to increase the height between the engaging plates. The connector may be a screw having a threaded portion. The first pin may include a threaded opening for receiving a threaded portion of the connector. The second pin may be connected to an unthreaded portion of the connector.

The pins preferably include a receiving section and an end. The ends of the pins are preferably sized to fit within the slots in the ribs of the engaging plates. The receiving section may have a width greater than that of the ends of the pins and preferably contains an opening for receiving the connector.

One engaging plate preferably includes a first slot that may terminate in an end that extends in a diverging direction from an end of another slot contained on the other engaging plate. Movement of one of the pins preferably draws the ends of the slots together to alter the amount of separation between the engaging plates. The movement of the pins relative to one another preferably alters the height proximate the anterior end at a faster rate than the height proximate the posterior end is altered to achieve a desired lordotic alignment.

In an alternate embodiment, the fusion device contains a load-sharing member to promote a spinal fusion. The load-sharing member may be axially disposed within the struts. The load-sharing member is preferably substantially deflectable to allow movement of one of the engaging plates when a compressive force is exerted on the engaging plates. A predetermined spacing preferably exists between the upper and lower members. Application of a compressive force onto the engaging plates preferably deflects the load-sharing member and decreases the predetermined spacing between the members, thereby decreasing the height of the strut. The deflection of the load-sharing member preferably imparts stress to bone graft proximate the engaging plates to promote the development and growth of bone in accordance with Wolff's law.

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The load-sharing member may be a pin having a circular cross-section and preferably is disposed in a bore extending axially through the strut. The bore preferably has a greater width than that of the load-sharing member to provide space for deflection of the load-sharing member. The load-sharing member may serve as a hinge-pin about which the upper member of the strut pivots with respect to the lower member of the strut.

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The fusion device preferably further includes a connector for engaging the load-sharing member to impart force to the load-sharing member to cause it to deflect. The strut may include a threaded opening in its end for receiving the connector. The predetermined spacing between the upper and lower members may be set to a desired length by altering the position of the connector in the opening in the end of the strut. The load-sharing member may include an indention having a substantially planar surface to provide a site for engagement with the connector. The connector preferably engages the load-sharing member at a fulcrum point located at a predetermined horizontal distance from a support location where the lower member of the strut contacts the load-sharing member. The material properties of the load-sharing member and the distance between the fulcrum point and the support location are preferably controlled such that the modulus of elasticity across the strut is substantially equal to the modulus of elasticity of bone.

In an alternate embodiment, the fusion device may include a bracket assembly separating the engaging plates and supporting the alignment device. The alignment device may include at least one screw coupled to at least one cam block. In the context of this description, "screw" refers generally to any elongated member having external threading. The cam block may include an opening through which the cam block is coupled to the screw. An inner surface of the opening may include threading that is complementary to the threading at an end of the screw. The threading of the screw and the threading of the cam block may form an engagement such that rotation of the screw in a first angular direction causes the cam block to move in a first lateral direction and such that rotation of the screw in an angular direction opposite the first angular direction causes the cam block to move in a lateral direction opposite the first lateral direction.

The inner face of each of the engaging plates may include sloped tracks. The cam block may include an upper surface and a lower surface. The surfaces of the cam block may be beveled or sloped to correspond to the slope of the tracks, such that the cam block fits into the tracks in the inner surfaces of the engaging plates. The surfaces of the cam block and the tracks in the inner faces of the engaging plates may be configured such that movement of the cam block toward the exterior of the fusion device increases the height between the engaging plates and such that movement of the cam block toward the interior of the fusion device decreases the height between the engaging plates. Alternatively, the surfaces of the cam block and the tracks in the inner faces of the engaging plates may be configured such that movement of the cam block toward the exterior of the fusion device decreases the height between the engaging plates and such that movement of the cam block toward the interior of the fusion device increases the height between the engaging plates.

Alternatively, in embodiments in which the fusion device includes more than one screw, the fusion device may include cam blocks and tracks in the engaging plates incorporating each of the above mentioned design elements.

The alignment device may include a single screw coupled to a single cam block. Alternatively, the alignment device may include a pair of screws, each of which is coupled to a single cam block. The screws

may be situated such that a first screw is substantially parallel to and substantially adjacent a first edge of the fusion device. A second screw may be situated substantially parallel to and substantially adjacent a second edge of the fusion device opposite the first edge. Alternatively, the first screw may be substantially parallel to and substantially adjacent a first edge of the fusion device, and the second screw may be substantially parallel to and substantially adjacent a second edge of the fusion device adjacent to the first edge. Alternatively, the alignment device may include three screws, each of which is coupled to a single cam block, such that a first screw is substantially parallel to and substantially adjacent a first edge of the fusion device. A second screw may then be situated substantially parallel to and substantially adjacent a second edge of the fusion device opposite the first edge, and a third screw may be situated substantially parallel to and substantially adjacent the first edge and the second edge. Alternatively, the first screw may be substantially parallel to and substantially adjacent a first edge of the fusion device, the second screw may be substantially parallel to and substantially adjacent a second edge of the fusion device, and the third screw may be substantially parallel to and substantially between the first and the second screws.

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In an alternate embodiment, the alignment device may include at least one screw coupled to a cam block as previously described, and the inner face of each of the engaging plates may include sloped tracks as previously described. A tip of each of the screws may be substantially unthreaded. The alignment device may further include a stationary block positioned between the engaging plates. The stationary block may include openings into which the unthreaded tip of each of the screws may be inserted. The stationary block may support each of the screws and preserve the engagement between the screws and the cam blocks during use.

The alignment device may include two screws, each of which is coupled to a cam block. The screws may be aligned such that the screws are positioned at an angle with respect to one another. Alternatively, the screws may be aligned such that the screws share a common axis of rotation. Two screws are said to share a "common axis of rotation" if the spatial relation of the longitudinal axes of rotation of the two screws is such that the longitudinal axis about which a first screw may be rotated and the longitudinal axis about which a second screw may be rotated are defined by the same line, irrespective of the physical dimensions (e.g., the diameters) of the screws or the longitudinal separation between the screws.

Alternatively, the alignment device may include three screws, each of which is coupled to a cam block. A first screw may share a common axis of rotation with a second screw, and a third screw may be aligned substantially perpendicular to the first screw and the second screw. Alternatively, the first screw may be oriented substantially perpendicular to the second screw, and the third screw may be oriented substantially at a first obtuse angle to the first screw and substantially at a second obtuse angle to the second screw. Alternatively, the first screw may be oriented substantially at a first non-perpendicular angle to the second screw and substantially at a second non-perpendicular angle to the third screw. Alternatively, the first screw may be oriented substantially parallel to the second screw, with the third screw situated between and substantially parallel to the first screw and the second screw.

Alternatively, the alignment device may include four screws, each of which is coupled to a cam block. A first screw may share a first common axis of rotation with a second screw, and a third screw may share a second common axis of rotation with a fourth screw. The first screw and the second screw may be situated substantially parallel to and substantially adjacent a first edge of the fusion device. The third screw and the fourth screw may be aligned substantially parallel to the first screw and the second screw and substantially adjacent an edge of the fusion device opposite the first edge. Alternatively, the first screw may share a common axis of rotation with the second screw, and the third screw may share a common axis of rotation with the fourth screw. The third screw and the fourth screw may be aligned substantially perpendicular to the first screw and the second screw. Alternatively, the first screw may share a common axis of rotation with the second screw and the third screw may share a common axis of rotation with the fourth screw. The third screw and the fourth screw may be aligned at a substantially non-perpendicular angle to the first screw and the second screw. The fusion device may be configured such that its cross-section is substantially rectangular. The first screw and the second screw may then be aligned substantially along a second diagonal of the rectangle intersecting the first diagonal.

In an alternate embodiment, the alignment device may include at least one screw configured to be coupled to a pair of cam blocks configured as described above. The inner face of each of the engaging plates may include sloped tracks as previously described. The screw may include a substantially unthreaded portion having a first diameter and a substantially threaded portion having a second diameter greater than the first diameter. Alternatively, the screw may include a substantially unthreaded portion having a first diameter and a substantially threaded portion having a second diameter substantially equal to the first diameter. Each of the cam blocks may include an opening through which the cam block is coupled to the screw. The inner surface of the opening in a first cam block may be substantially unthreaded. The inner surface of the opening in a second cam block may include threading that is complementary to the threading of the screw. The bracket assembly may include projections into the interior of the fusion device and having inner surfaces having threading that is complementary to the threading of the screw in a first angular direction may thus cause the screw to move in a first lateral direction with respect to the bracket assembly, and rotation of the screw in an angular direction opposite the first angular direction may thus cause the screw to move in a lateral direction opposite the first lateral direction.

The unthreaded opening in the first cam block may be substantially similar in diameter to the diameter of the unthreaded portion of the screw. The unthreaded portion of the screw may pass through the opening in the first cam block such that the screw is free to rotate within the opening in the first cam block. The screw may further include a flange coupled to the screw at a first end of the screw adjacent the unthreaded portion of the screw. The first end of the screw may include an indentation sized and shaped such that a tip of an adjusting tool may be inserted into the indentation. The adjusting tool may be a screwdriver. Preferably, the adjusting tool is an allen wrench. The adjusting tool may be used to rotate the screw. The diameter of the threaded portion of the screw and the diameter of the flange may be sufficiently larger than the diameter of the opening in the first cam block such that coupling is maintained between the first cam block

and the screw as the screw is rotated (i.e., the screw remains inserted in the opening through the first cam block) and such that the first cam block is constrained to move laterally in the same direction as the screw when the screw is rotated. The threading of the screw and the threading of the second cam block may form an engagement between the second cam block and the screw such that rotation of the screw causes the second cam block to move in a lateral direction opposite the direction of lateral motion of the screw.

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The alignment device may include a single screw coupled to a pair of cam blocks and situated substantially parallel to and substantially adjacent an edge of the fusion device. Alternatively, the alignment device may include a pair of screws that are each coupled to a pair of cam blocks. The screws may be situated such that a first screw is substantially parallel to and substantially adjacent a first edge of the fusion device. A second screw may be situated substantially parallel to and substantially adjacent a second edge of the fusion device opposite the first edge. Alternatively, the first screw may be situated substantially parallel to and substantially adjacent a first edge of the fusion device and the second screw may be situated substantially parallel to and substantially adjacent a second edge of the fusion device adjacent to the first edge. Alternatively, the alignment device may include three screws, each of the screws being coupled to a pair of cam blocks, such that a first screw is substantially parallel to and substantially adjacent a first edge of the fusion device. A second screw may then be situated substantially parallel to and substantially adjacent a second edge of the fusion device opposite the first edge, and a third screw may be situated substantially parallel to and substantially perpendicular to the first edge and the second edge.

In an alternate embodiment, the screw in the alignment device may be a turnbuckle. In the context of this description, "turnbuckle" refers to a screw having external threading in a first direction at a first end and external threading in a direction opposite the first direction at a second end opposite the first end. The turnbuckle may be coupled to a pair of cam blocks via threaded openings in the cam blocks. An inner surface of each of the openings may include threading that is complementary to the threading at one of the ends of the turnbuckle. The threading of the turnbuckle and the threading of the cam blocks may form an engagement such that rotation of the turnbuckle in a first direction causes the cam blocks to move away from each other and such that rotation of the turnbuckle in a direction opposite the first direction causes the cam blocks to move toward each other. The inner face of each of the engaging plates may include sloped tracks as previously described. At least one end of the turnbuckle may include an indentation sized and shaped such that a tip of an adjusting tool may be inserted into the indentation. The adjusting tool may be a screwdriver. Preferably, the adjusting tool is an allen wrench. The adjusting tool may be used to rotate the turnbuckle.

The turnbuckle may include a middle portion disposed between the first end and the second end and having a thickness greater than a thickness of the first end and a thickness of the second end. The bracket assembly may include lateral projections into the interior of the fusion device. The middle portion of the turnbuckle may be configured to fit between the lateral projections from the bracket assembly. The lateral projections may include openings of a size sufficient to allow the ends of the turnbuckle to pass through without allowing the middle portion to pass through, thus maintaining the turnbuckle in the bracket assembly.

The alignment device may include a single turnbuckle coupled to a pair of cam blocks and situated substantially parallel to and substantially adjacent an edge of the fusion device. Alternatively, the alignment device may include a pair of turnbuckles that are each coupled to a pair of cam blocks. The turnbuckles may be situated such that a first turnbuckle is substantially parallel to and substantially adjacent a first edge of the fusion device. A second turnbuckle may be situated substantially parallel to and substantially adjacent a second edge of the fusion device opposite the first edge. Alternatively, the first turnbuckle may be substantially parallel to and substantially adjacent a first edge of the fusion device, and the second turnbuckle may be substantially parallel to and substantially adjacent a second edge of the fusion device adjacent to the first edge. Alternatively, the alignment device may include three turnbuckles that are each coupled to a pair of cam blocks, such that a first turnbuckle is substantially parallel to and substantially adjacent a first edge of the fusion device. A second turnbuckle may then be situated substantially parallel to and substantially adjacent a second edge of the fusion device opposite the first edge, and a third turnbuckle may be situated substantially perpendicular to the first edge and the second edge.

The above embodiments may be used independently or in combination.

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An advantage of the invention relates to an intervertebral body fusion device that substantially maintains the natural lordosis of the human spine.

Another advantage of the invention relates to an intervertebral body fusion device adapted to correct a lateral deviation in the spinal column.

Anther advantage of the invention relates to an intervertebral body fusion device that substantially maintains the natural lordosis of the human spine while simultaneously being adapted to correct a lateral deviation in the spinal column.

# BRIEF DESCRIPTION OF THE DRAWINGS

Further advantages of the present invention will become apparent to those skilled in the art with the benefit of the following detailed description of the preferred embodiments and upon reference to the accompanying drawings in which:

- FIG. 1 depicts a conventional intervertebral body fusion implant positioned between neighboring vertebrae;
- FIG. 2 depicts another conventional intervertebral body fusion implant that includes a pair of cylindrical members positioned between neighboring vertebrae;
  - FIG. 3 depicts a top view of a fusion device located on a vertebral body;
  - FIG. 4a depicts a cross-sectional view of the fusion device of FIG. 3 taken along plane I;
- FIG. 4b depicts a cross-sectional view of the fusion of FIG. 3 device taken along plane I wherein the fusion device contains bone graft and has been adjusted to maintain a substantially natural lordosis;

	FIG. 5 depicts a front view of a fusion device;
_	FIG. 6a depicts a perspective view of a strut;
5	FIG. 6b depicts a side view of a tapered strut;
	FIG. 7 depicts a top view of a fusion device:
10	FIG. 8 depicts a front view of a pair of engaging plates;
	FIG. 9 depicts a front view of a fusion device having pivotable struts;
	FIG. 10 depicts a top view of a fusion device containing a connector;
15	FIG. 11 depicts an anterior view of a fusion device having a connector and cam pins;
	FIG. 12 depicts a cross-sectional view taken along plane III of FIG. 11 of the fusion device in a lowered position;
20	FIG. 13 depicts a cross-sectional view taken along plane III of FIG. 11 of the fusion device in a raised position;
25	FIG. 14 depicts a cross-sectional view taken along plane IV of FIG. 11 of the fusion device in a lowered position:
	FIG. 15 depicts a cross-sectional view taken along plane IV of FIG. 11 of the fusion device in a raised position;
30	FIG. 16 depicts a side view of a fusion device disposed between vertebrae;
	FIG. 17 depicts a top view of a strut having a tapered end;
35	FIG. 18 depicts a cross-sectional view taken along plane V of FIG. 17 of the strut in an unloaded position;

FIG. 19 depicts a cross-sectional view taken along plane V of FIG. 17 of the strut in a loaded

position;

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FIG	20 depicts a top	view of a	fusion device	located on	a vertebral bo	dv:
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- FIG. 21 depicts a cross-sectional view of the fusion device taken along plane VI of FIG. 3;
- FIG. 22 depicts a top view of a conventional fusion cage having a pair of cylindrical elements disposed on a vertebra;
- FIG. 23 depicts a side view of one of the cylindrical elements in FIG. 22 disposed between neighboring vertebrae;
  - FIG. 24 depicts a front view of the cylindrical element in FIG. 23;
- FIG. 25 depicts a perspective view of a fusion device in the lowered position, the fusion device including a pair of tumbuckles oriented perpendicular to the anterior and posterior edges of the fusion device;
  - FIG. 26 depicts a perspective view of the fusion device of FIG. 25 in the raised position;
  - FIG. 27 depicts an exploded view of the fusion device of FIG. 25;

FIG. 28 depicts a perspective view of a bracket assembly of the fusion device of FIG. 25;

- FIG. 29a depicts a perspective view of the end of the bracket assembly of FIG. 25;
- 25 FIG. 29b depicts a perspective view of a cam block of the fusion device of FIG. 25:
  - FIG. 29c depicts a side view of the cam block of FIG. 29b;
  - FIG. 30a depicts a cutaway view of the fusion device of FIG. 25 in a lowered position;
  - FIG. 30b depicts a cutaway view of the fusion device of FIG. 25 in a raised position;
  - FIG. 31a depicts a cutaway view of an alternative configuration of the fusion device of FIG. 25 in a lowered position;
  - FIG. 31b depicts a cutaway view of an alternative configuration of the fusion device of FIG. 25 in a raised position;
    - FIG. 32a depicts a top view of the alignment device of FIG. 25 in use;

FIG. 32a depicts a front view of the alignment device of FIG. 25 in use in a lowered position; FIG. 32c depicts a front view of the alignment device of FIG. 25 in use in a raised position; 5 FIG. 33 depicts an exploded view of a fusion device including a pair of turnbuckles oriented parallel to the anterior and posterior edges of the fusion device; FIG. 34 depicts a perspective view of the bracket assembly of the fusion device of FIG. 32; 10 FIG. 35 depicts an exploded view of a fusion device including a pair of screws, each of which is threaded through a pair of cam blocks; FIG. 36 depicts a perspective view of the alternative bracket assembly of the fusion device of FIG. 15 34; FIG. 37a depicts a cross-sectional view of the screws and cam blocks of FIGs. 35-36 in use in a first position; FIG. 37b depicts a cross-sectional view of the screws and cam blocks of FIGs. 35-36 in use in a 20 second position; FIG. 38 depicts an exploded view of a fusion device including three turnbuckles; FIG. 39 depicts a perspective view of the bracket assembly of the fusion device of FIG. 38; 25 FIG. 40 depicts an exploded view of a fusion device including three substantially parallel screws; FIG. 41 depicts a perspective view of the bracket assembly of the fusion device of FIG. 40; 30 FIG. 42 depicts an exploded view of a fusion device including three non-parallel screws; FIG. 43a depicts a perspective view of the bracket assembly of the fusion device of FIG. 42; FIG. 43b depicts a cross-sectional view of a screw, a cam block, and the stationary block of FIG. 42; 35 FIG. 44 depicts an exploded view of a fusion device including four screws oriented as two parallel pairs;

FIG. 45 depicts a perspective view of the bracket assembly of the fusion device of FIG. 42;

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FIG. 46 depicts an exploded view of a	fusion device including four screws orio	riented in a "+"	
configuration;	· · · · ·		

- FIG. 47 depicts a perspective view of the bracket assembly of the fusion device of FIG. 46;
- FIG. 48 depicts an exploded view of a fusion device including four screws oriented in an "x" configuration;
  - FIG. 49 depicts a perspective view of the bracket assembly of the fusion device of FIG. 48;
- FIG. 50a depicts a perspective view of a fusion device including one screw and at least one cam block in a lowered position;
  - FIG. 50b depicts a perspective view of the fusion device of FIG 50a in a raised position;
  - FIG. 50c depicts an exploded view of the fusion device of FIG. 50a;
- FIG. 51a depicts a cutaway view of an embodiment of a bracket assembly of the fusion device of FIG. 50a;
  - FIG. 51b depicts a cross-sectional view of a turnbuckle of the bracket assembly of FIG 51a;
- FIG. 51c depicts a cutaway view of an alternative embodiment of a bracket assembly of the fusion device of FIG. 50a;
  - FIG. 51d depicts a cross-sectional view of a turnbuckle of the bracket assembly of FIG 51c;
  - FIG. 52a depicts a top view of the fusion device of FIG. 50a in use; and
  - FIG. 52b depicts a side view of a pair of the fusion devices of FIG. 50a in use.

While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof are shown by way of example in the drawings and will herein be described in detail. It should be understood, however, that the drawings and detailed description thereto are not intended to limit the invention to the particular form disclosed, but on the contrary, the intention is to cover all modifications,

equivalents and alternatives falling within the spirit and scope of the present invention as defined by the

appended claims.

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# DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A preferred embodiment of an interbody fusion implant device 10 for facilitating the formation of a spinal fusion is depicted in FIGs. 3-5. A top view of the fusion device is depicted in FIG. 3. Fusion device 10 preferably includes a pair of sides or engaging plates 12 and 14 for engaging vertebral bodies 16 and 18. The engaging plates may contain curved edges such that the outer face 15 of the plates conforms to the shape of the cross-section of the vertebral bodies as shown in FIG. 3. The fusion device has a height 20 defined by the vertical distance between the outer faces 15 of the engaging plates 12 and 14. The height 20 of the fusion device is preferably adjustable and may vary along the fusion device between anterior end 22 and posterior end 24 to maintain the natural lordosis of the spine. Height 20 may also vary along device 10 from first side 26 to second side 28 to correct for a lateral deviation in the spine as may occur in scoliosis. Fusion device 10 preferably further includes an alignment device for adjusting the height 20 so that the natural lordosis of the spine is substantially maintained after the fusion device is implanted. The alignment device may be used to adjust the height between the engaging plates proximate the anterior end and independently adjust the height between the engaging plates proximate the natural or end.

A spinal fusion is typically employed to eliminate pain caused by the motion of degenerative disk material. Upon successful fusion, fusion device 10 becomes permanently fixed within the disc space. The fusion device is preferably packed with bone graft 40 to promote the growth of bone through and around the fusion device. Such bone graft may be packed between engaging plates 12 and 14 prior to, subsequent to, or during implantation of the fusion device. Bone substitute material that is well known to those skilled in the art may be used instead of bone graft. A bone harvester kit, commercially available from Spine-Tech, Inc. located in Minneapolis, MN, may be used to inject bone graft between the engaging plates. The pamphlet entitled "Bone Harvester: Minimally Invasive Bone Harvesting Kit" (available from Spine-Tech, Inc.) details the use of the bone harvesting kit.

In an embodiment of the invention, the faces 15 of engaging plates 12 and 14 contain a plurality of openings 34 disposed therein to allow bone development and growth through the engaging plates 12 and 14 and between fusion device 10 and neighboring vertebrae 16 and 18. In an embodiment, the openings 34 have a combined area that is greater than about 50 percent of the area of face 15 (including the area of the openings 34), more preferably between about 60 percent and about 80 percent of the area of face 15, and more preferably still about 70 percent or more of the area of face 15.

The fusion device may contain a retaining plate 36 proximate posterior end 24 to provide a backing against which bone graft may be packed and to maintain the bone graft between the engaging plates. Retaining plate 36 may be substantially planar and may contain openings to allow bone ingrowth therethrough. A removable endcap 25 may be positioned proximate anterior end 22 to contain bone graft within the fusion device and to prevent the migration of bone graft outside the engaging plates. The endcap 25 may contain one or more openings for allowing bone ingrowth between a vertebral body and bone graft

contained between the engaging plates. Endcap 25 is preferably made of a plastic material such as polyethylene that tends to be non-irritating and non-abrasive to the surrounding tissues.

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A cross section of the fusion device taken through plane I of FIG. 3 is depicted in FIG. 4a and FIG. 4b. FIG. 4a shows the relative position of engaging plates 12 and 14 before height 20 has been adjusted with an alignment device to achieve a substantially natural lordosis. FIG. 4b shows the relative position of the plates after height 20 has been adjusted and bone graft 40 has been packed between the engaging plates. FIG. 4b shows that height 20 is greater in the vicinity of anterior end 22 as compared to posterior end 24 to maintain the natural lordosis of the spinal column. The faces 15 of the engaging plates 12 and 14 are preferably planar to provide a relatively large contact area between the engaging plates and the neighboring vertebrae. In this manner, subsidence of the vertebrae may be prevented because the force imparted to the vertebrae from the fusion device is not concentrated across a relatively small area of the vertebrae as in some conventional implants. Alternately, the engaging plates may be non-planar. The engaging plates also preferably contain a plurality of spikes or protrusions 38 extending from the face 15 for enhancing an engagement between the vertebra and the engaging plate. The protrusions may extend into the vertebra to prevent the fusion device from moving out of the disc space. The engaging plates are preferably constructed of titanium or a titanium alloy, although it is to be understood that other materials (e.g., ceramics, metals, carbon composites) may be used.

A front view of the fusion implant device is depicted in FIG. 5. In an embodiment of the invention, the alignment device includes a first strut 30 and a second strut 32 that each extend between engaging plates 12 and 13 along the length of the fusion device from anterior end 22 to posterior end 24. As described herein, a "strut" is taken to mean any support member disposed between the engaging plates to separate the engaging plates. Strut 30 preferably extends along the fusion device proximate first side 26. Strut 32 is preferably substantially parallel to strut 30 and may extend along the fusion device proximate second side 28. The struts 30 and 32 serve to create a predetermined spacing between the engaging plates. The predetermined spacing is preferably such that the height 20 is approximately equal to the height of the disc material that formerly occupied the disc space between the vertebral bodies.

A perspective view of an embodiment of the strut is depicted in FIG. 6a. The strut may have an "I-beam" shape and preferably includes a pair of ends 50. The ends 50 may have a lateral width 51 that is greater than that of the sides 53. The ends preferably have a "dovetail" shaped cross-section as shown in FIG. 6a. The engaging plates preferably contain elongated slots 60 (shown in FIGs. 7 and 8) sized to receive ends 50 of the first and second struts. The slots 60 preferably have a complementary dovetail shape as depicted in FIG. 8 that conforms to the shape of the end 50. The struts may be connected to the engaging plates by sliding ends 50 into the slots 60 in a direction from anterior end 22 to posterior end 24 or vice versa.

In an embodiment, the slots are tapered such that their width narrows in a direction from the anterior end to the posterior end as shown in FIG. 7. The ends 50 may be tapered (as shown in FIG. 17) such that the lateral width 51 narrows along the length of the strut. The taper of the lateral width of the strut preferably matches that of slot.60. The width of the slot proximate the anterior end is preferably sized to allow the strut end to be slid into the slot. The width of the slot proximate the posterior end is preferably less than the lateral

width 51 of the narrowest portion of end 50. The tapering of the slots preferably allows a "locking taper engagement" of the strut ends within the slots. A "locking taper engagement" is taken to mean a fixable interference fit formed between end 50 and slot 60 whereby the strut resists dislodgment when force is imparted to the fusion device from the adjacent vertebrae. In an alternate embodiment, the slots may be tapered such that the width of the slots narrows in a direction from the posterior end to the anterior end.

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The first and second struts preferably each have a predetermined height that defines the height of the fusion device. The engaging plates 12 and 14 are preferably adapted to receive struts of various heights to allow height 20 to be varied to fit the needs of the patient. A side view of a tapered strut is depicted in FIG. 6b. The tapered strut preferably has a height that varies along its length. In this manner, the tapered strut is positionable between the engaging plates 12 and 14 to cause height 20 to decrease in a direction from anterior end 22 to posterior end 24 whereby the natural lordosis of the human spine is maintained by the fusion device. The degree of taper of the strut corresponds to a desired lordosis and may vary depending upon the size of the patient.

In an embodiment, the first and second struts have differing heights to cause height 20 to vary between first end 14 and second end 16. In this manner, the fusion device may be used to correct a lateral deviation in the spinal column as may occur in scoliosis. A front view of a fusion device containing struts having different heights is depicted in FIG. 9. Each of the struts preferably contains a hinge pin 70 to allow an upper member 72 of the strut to pivot with respect to a lower member 74 of the strut. In this manner, the struts may be pivoted as shown in FIG. 9 such that the ends of the struts are properly aligned with the slots of the engaging plates when a height difference exists between the first and second struts.

To install the fusion device, a discectomy is preferably performed from an anterior approach. All cartilage and soft tissue are preferably removed from the vertebral endplate as would normally be done for placement of a femoral strut graft. Such a procedure is well within the knowledge of a skilled practitioner of the art. The engaging plates may be deployed in the disc space between the adjacent vertebrae. A distraction force may be applied to the engaging plates using a laminae spreader or similar device to force the vertebrae to a selected height and lordotic alignment. The use of a laminae spreader is well known to those skilled in the art. The proper heights for the first and second struts may be determined beforehand using x-ray techniques in which the posterior and anterior portions of the intervertebral disc space are examined.

Appropriately sized and tapered struts are preferably slipped into slots 60 and tapped until a locking taper engagement is achieved between the strut ends and the slots. If struts of differing heights are used to correct for a lateral deviation in the spinal column, each strut may be pivoted about hinge pin 70 prior to insertion so that ends 50 are properly aligned for placement into grooves 60. Bone graft material is preferably inserted through the anterior end and packed between the engaging plates. Retaining plate 36 preferably prevents the bone graft material from passing through the fusion device during packing. Endcap 25 may then be placed onto the anterior end.

In an alternate embodiment depicted in FIGs. 10-16, the alignment device includes a connector 80 for adjusting the height 20 of the plates to achieve a desired lordotic alignment. FIG. 10 depicts a top view of the fusion device. Connector 80 is preferably a drive screw that is rotatable to adjust height 20. Connector 80

preferably extends between engaging plates 12 and 14 and may be adapted to move axially through the fusion device in a direction from anterior end 22 to posterior end 24. The engaging plates may contain elongated openings 82 for allowing bone growth through the faces 15 of the plates.

FIG. 11 depicts a front (anterior) view of the fusion device in a raised position. In an embodiment, the engaging plates include ribs 84 and 85 that may extend substantially perpendicularly from face 15. A cross-sectional view taken along plane III of FIG. 11 is depicted in each of FIG. 12 and FIG. 13. FIG. 12 depicts rib 84 and cam pins 86 and 88 in section with the fusion device in a "lowered position" (i.e., unadjusted for lordotic alignment). FIG. 13 depicts the rib and cam pins in section with the fusion device in the "raised position" (i.e., adjusted for lordotic alignment). As described herein, "cam pin" is taken to mean any connecting element capable of extending from the connector into the slots 90 and 92. Each of the cam pins may be intersected by an imaginary longitudinal axis 91 axially extending through the fusion device.

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Rib 84 preferably contains a slot 90 having a first end and a second end. The ends of slot 90 preferably terminate in a direction below axis 91. The first end of slot 90 preferably extends downwardly substantially toward either the face of engaging plate 14 or the anterior end. The second end of slot 90 preferably extends downwardly substantially toward either the face of engaging plate 14 or the posterior end. Rib 85 preferably contains a slot 92 having a pair of ends that extend in diverging directions from the slot ends of rib 84. The ends of slot 92 preferably terminate in a direction above axis 91. The first end of slot 92 preferably extends upwardly substantially toward either the face of engaging plate 12 or the anterior end. The second end of slot 90 preferably extends upwardly substantially toward either the face of engaging plate 12 or the posterior end. The engaging plates are preferably connected together with cam pins 86 and 88, which preferably have ends sized to fit within slots 90 and 92. The cam pins preferably are disposed through the fusion device in a direction from the first side to the second side. Pins 86 and 88 preferably contain a receiving section 87 having an opening for receiving connector 80. Receiving section 87 may have a greater width (e.g., diameter) than the ends of pins 86 and 88 disposed in slots 90 and 92.

FIG. 14 and FIG. 15 each depict a cross-sectional view of the fusion device taken along plane IV of FIG. 11. FIG. 14 depicts the connector and cam pins in section with the fusion device in the lowered position. FIG. 15 depicts the connector and the cam pins in section with the fusion device in the raised position. In an embodiment, connector 80 contains a threaded portion 94 and an unthreaded portion 96. Pin 86 is preferably connected to the threaded portion and pin 88 is preferably connected to the unthreaded portion.

In an embodiment, a torque delivered to the connector is converted into a separation force between the cam pins. Rotating the connector in a counterclockwise direction preferably moves the connector in a direction from the anterior end to the posterior end. Pin 88 is preferably attached to the connector and preferably moves in the same manner as the connector. Pin 86 preferably contains an opening having complementary threading to that of the connector. Pin 86 preferably moves toward the anterior end in a direction opposite the motion of the connector to increase the separation between pin 88 and pin 86. The ends of the pins preferably move along the angled portions of the slots 90 and 92, causing the ends of the slots to be drawn together. In this manner, the separation between the engaging plates is increased. The connector may

be rotated in a counterclockwise direction to move the connector in a direction from the posterior end to the anterior end, thereby decreasing height 20.

Conventional methods of surgically implanting fusion devices tend to require that distraction instruments be inserted between the vertebrae to separate them and allow insertion of the fusion device therebetween. The surgical incision typically must be widened to accommodate the distraction instruments. In an embodiment, the fusion device in the lowered position has a height that is less than the disc space between the vertebrae. In this manner, the fusion device may be inserted between the vertebrae with minimal distraction. Connector 80 is preferably operable to separate the engaging plates (hence the vertebrae) and create a desired lordotic alignment.

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The distance that the engaging plates are separated per unit torque applied to the connector will tend to depend upon the angle of the slots 90 and 92. The slots are preferably angled such that the height 20 proximate the anterior end changes at a greater rate than the height 20 proximate the posterior end when the connector is adjusted to alter the distance between the plates. In this manner, a desired lordotic alignment may be achieved. It is to be understood that the fusion device is operable in a semi-raised position that is intermediate the raised and lowered positions depicted in FIGs. 12-15. The connector is preferably rotated to a selected degree to achieve a preferred height 20 proximate the anterior and posterior ends to suit the particular patient. The angle of the slots 90 and 92 may vary among patients and is preferably selected to achieve a desired lordotic alignment. The connector may include a retaining ring 98 for contacting one or both of the engaging plates to limit the degree to which the connector can move through the fusion device.

FIG. 16 depicts a side view of an alternate embodiment of the fusion device installed between neighboring vertebrae. Pin 86 may be located on the unthreaded portion of the shank adjacent to the head of connector 80. Pin 88 may be located on threaded portion 94 of the shank of connector 80. Rib 84 preferably includes a first slot 100 that is angled diagonally upward from axis 91 in a direction substantially toward either the face of engaging plate 12 or the anterior end 22. Rib 84 preferably also includes a second slot 102 that is angled diagonally upward from axis 91 in a direction substantially toward either the face of engaging plate 12 or the posterior end 24. Rib 85 preferably includes a first slot 104 that is angled diagonally downward from axis 91 in a direction substantially toward either the face of engaging plate 14 or the anterior end 22. Rib 85 preferably also includes a second slot 106 that is angled diagonally downward from axis 91 in a direction substantially toward either the face of engaging plate 14 or the posterior end 24. To adjust the fusion device into the raised position, the connector may be rotated to cause the cam pins to be moved in a direction toward one another. Pin 86 preferably moves with the connector in a direction from the anterior end to the posterior end to increase the separation between the engaging plates proximate the anterior end. Pin 88 preferably contains a threaded opening for receiving the connector and may move in a direction toward the posterior end to increase the separation between the engaging plates proximate the posterior end.

In an alternate embodiment, each of the pins 86 and 88 contains a threaded opening for receiving the connector 80. The connector may be a "double-threaded" screw having two threaded portions for complementing the threaded openings of the pins 86 and 88. Rotation of the screw in a first direction preferably causes the pins to move toward one another to increase the separation between the engaging plates.

Rotation of the screw in an opposite direction preferably causes the pins to move away from one another to reduce the separation between the engaging plates.

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In an alternate embodiment, the alignment device includes a load-sharing member to allow the engaging plates to move in response to a compressive force of predetermined magnitude. In accordance with Wolff's law, bone growth tends to occur in the presence of stress (e.g., load), and bone tends to be absorbed in the absence of stress. The load-sharing member preferably enables the fusion device to "share" compressive forces exerted onto the spinal column with the bone graft in the vicinity of the fusion device. The load-sharing member preferably is deflected upon receiving a predetermined force to cause the engaging plates to move, thereby shifting load from the fusion device to the bone graft proximate the fusion device. It is believed that providing a selected amount of stress to the bone graft in a such a manner will tend to result in a higher fusion rate as well as a stronger fusion mass.

An embodiment of the load-sharing fusion device is depicted in FIGs. 17-19. A top view of a strut 30 containing a load-sharing member is depicted in FIG. 17. FIGs. 18 and 19 depict cross-sectional views of the strut taken along plane V of FIG. 17. Load-sharing member 110 is preferably disposed axially through the strut. The load-sharing member may be contained in a bore extending into the strut. The bore preferably has a width (e.g., diameter) that is greater than that of the load-sharing member to allow sufficient space for the load-sharing member to be deflected. The bore is preferably disposed within lower member 74. Portion 118 of the upper member may substantially surround the bore and the load-sharing member, thereby allowing attachment of the upper and lower members. In an embodiment, the load-sharing member is a pin having a substantially circular cross-section. The pin preferably fits loosely within the bore such that its rotational freedom is maintained. The pin may be hinge pin 70 about which the upper member 72 pivots with respect to the lower member 74. The load-sharing member preferably contains an indention 114 forming a substantially planar surface about which the load-sharing member may be deflected.

A connector 112 preferably extends through an opening 116 in the end 50 of the strut. The connector preferably fixes the load-sharing member to the upper member 72 and may contact the load-sharing member at fulcrum point 126, which is preferably located on the planar surface formed by indention 114. Connector 122 is preferably a set screw, and opening 116 preferably contains threading for engaging the set screw. FIG. 18 depicts the strut in an "unloaded" position whereby a predetermined spacing 122 exists between upper member 72 and portion 120 of lower member 74. The predetermined spacing 122 may be adjusted by altering the location of connector 112 within opening 116. For instance, the screw may be rotated through opening 116 to increase spacing 122. The load-sharing member preferably remains substantially undeflected in the unloaded position.

Upon application of a compressive force onto the end 50 of the upper member 72, force is preferably imparted from connector 112 to the load-sharing member at fulcrum point 126. The compressive force is preferably sufficient to cause deflection of the load-sharing member and movement of upper member 72 toward portion 120 of the lower member such that predetermined spacing 122 is decreased. The deflection of the load-sharing member may force portion 118 of the upper member into a cavity 115 formed within the

axial bore. The load-sharing member is preferably deflected in a three point bending arrangement as shown in FIG. 19.

FIG. 19 depicts the strut in the "loaded" position with the load-sharing member deflected. The predetermined spacing 22 is preferably adjustable and may be adjusted to set the maximum strain that can be imparted to the load-sharing member. When the load-sharing member has been deflected a vertical distance equal to predetermined spacing 22, the upper member 72 contacts portion 120, thereby inhibiting further strain on the load-sharing member. In this manner, the maximum amount of strain on the load-sharing member can be limited to reduce the possibility that the member will experience fatigue failure.

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The load-sharing member may be constructed of any of a variety of metals or allovs. In a preferred embodiment, the load-sharing member is constructed of titanium or a titanium alloy. The material properties and cross-sectional area of the load-sharing member are preferably controlled to allow a predetermined amount of stress to occur across the fusion device. The horizontal distance 124 or moment arm between fulcrum point 126 and support point 128 on the lower member is preferably selected such that the fusion device has an "effective" modulus of elasticity in the vicinity of the modulus of elasticity of bone to facilitate bone development. The "effective" modulus of elasticity of the fusion device is taken to mean the ratio of stress to strain across the fusion device in a direction along height 20 as the device moves from the unloaded position to the loaded position upon receiving a compressive force. As described herein, "in the vicinity of the modulus of elasticity of bone" is taken to mean a Young's modulus between about 3 GPa and about 25 GPa. In an embodiment, the effective modulus of the fusion device is between about 16 GPa and about 20 GPa. The paper entitled "Variation of Young's Modulus and Hardness in Human Lumbar Vertebrae Measured by Nanoindentation" by Marcel Roy and Jae-Young Rho (Department of Biomedical Engineering, University of Memphis, Memphis, TN), and Ting Y. Tsui and George M. Pharr (Department of Materials Science, Rice University, Houston, TX) relates to the mechanical properties of bone and is incorporated by reference as if fully set forth herein.

The stresses exerted onto the spinal column are preferably shared by the fusion device and surrounding bone graft. As the spinal fusion develops, the proportion of stress experienced by the surrounding bone material preferably increases and the required load on the fusion device preferably decreases. After completion of the fusion, the fusion device preferably remains in the unloaded position during normal daily activity of the patient.

Fusion device 10 preferably provides a relatively large contact area between the engaging plates and the vertebral bodies defining the disc space occupied by the fusion device. FIG. 20 depicts a top view of an embodiment of a fusion device of the present invention. FIG. 21 depict a cross-sectional view of the fusion device taken along plane VI of FIG. 20. Depicted in FIGs. 22-24 is a conventional fusion cage such as that described in U.S. Patent No. 4,961,740 to Ray et al. This patent is incorporated by reference as if fully set forth herein. The devices in FIGs. 20-24 are sized for use in the L3-L4 disc space of an average size middle-aged female. Dimensions of the fusion devices are indicated in millimeters.

The "effective contact area" between an engaging plate and a vertebral body may be calculated by subtracting the fenestration area, a (i.e., the combined area of the openings 34 intended for bone ingrowth),

from the total contact area, A (the area of the face 15 including the area of the openings 34). The total contact area and the fenestration area of the fusion device in FIGs. 20 and 21 is 581 mm<sup>2</sup> and 96 mm<sup>2</sup>, respectively. Therefore, the effective contact area between the engaging plate and the vertebra is 485 mm<sup>2</sup>.

For the fusion cage depicted in FIGs. 22-24, it is assumed that threads on the outer surface of the fusion cage penetrate into the vertebra a total of 3 mm per side as recommended by the manufacturer. It should be noted that such penetration is often difficult to achieve. In addition, the cortical layer of a vertebral body is often only 1-2 mm thick. Each of the cylindrical elements of the fusion cage has a total contact area of 283.5 mm<sup>2</sup> and a fenestration area of 198.5 mm<sup>2</sup>. Therefore, the combined effective contact area of both of the cylindrical elements is 170 mm<sup>2</sup>. If the threads of the fusion cage penetrate into the vertebra a distance less than 3 mm per side, the contact area will be less than that calculated above.

The maximum axial compressive forces in the lumbar spine resulting from everyday activity were estimated to be 3200 N in a paper entitled "The BAK<sup>TM</sup> Interbody Fusion: An Innovative Solution" by Bagby et al. and available from Spine Tech, Inc. in Minneapolis Minnesota (see page 3, bottom paragraph). For a 3200 N compressive force, the stress per unit area is calculated to be 18.8 N/mm² for the fusion cage depicted in FIGs. 22-24 as compared to 6.6 N/mm² for the fusion device depicted in FIG. 20 and FIG. 21. It is believed that such a reduction in stress per unit area will result in a significant reduction in post surgical subsidence at the interface of the fusion device and vertebral body. Typically, the loss of disc height is estimated to be about 1-3 mm at one month follow-up when conventional devices such as that depicted in FIGs. 22-24 are employed.

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# **FURTHER IMPROVEMENTS**

An alternate embodiment of an interbody fusion device is depicted in FIGs. 25-27. FIG. 25 is a perspective view of the fusion device in a lowered position. FIG. 26 is a perspective view of the fusion device in a raised position. FIG. 27 is an exploded view of the fusion device. Fusion device 200 includes a pair of engaging plates 202 and 204 for engaging adjacent vertebrae. Engaging plates 202 and 204 are preferably separated by bracket assembly 206. Engaging plates 202 and 204 and bracket assembly 206 may be formed of titanium, stainless steel, polymer, ceramic, composite material, or any other biocompatible material. For purposes of this description, "biocompatible material" is material not rejected by the body and/or not causing infection following implantation.

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As depicted in FIG. 27, engaging plates 202 and 204 may contain a plurality of protrusions 216 from outer surfaces 203 for enhancing an engagement between the vertebrae and the engaging plates. In this manner, subsidence of the vertebrae may be substantially prevented as previously described. Outer surfaces 203 are preferably substantially planar to provide a large contact area between the engaging plates and the vertebrae; alternately, outer surfaces 203 may be non-planar. Protrusions 216 may extend into the vertebrae to prevent the fusion device from moving out of the disc space. Engaging plates 202 and 204 may include a plurality of openings 218 to allow bone development and growth through the engaging plates and between fusion device 200 and the neighboring vertebrae. In an embodiment, openings 218 have a combined area that is greater than about 50% of the total area of outer surfaces 203 (including the area of openings 218). More

preferably, openings 218 have a total area between 60% and 80% of the total area of outer surfaces 203. More preferably still, openings 218 have a total area of 70% or more of the total area of outer surfaces 203.

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Bracket assembly 206 (depicted in perspective view in FIG. 28) preferably includes an alignment device for changing a height between engaging plates 202 and 204. In an embodiment, the alignment device includes first turnbuckle 250 and second turnbuckle 270 positioned substantially parallel to and substantially adjacent first side edge 212 and second side edge 214, respectively, and extending between anterior edge 208 and posterior edge 210. Bracket assembly 206 includes lateral projections 244 and 246 extending into the interior of the bracket assembly and supporting turnbuckles 250 and 270, respectively. The turnbuckles include middle portions (e.g., middle portion 256 of turnbuckle 250) disposed between the ends of the turnbuckles and having a diameter greater than a diameter of the threaded portions. Lateral projection 244 is sized such that middle portion 256 is retained within lateral projection 244 while turnbuckle 250 is free to rotate within lateral projection 244. Ends 296 of bracket assembly 206 (shown in detail in FIG. 29A) may include arcuate grooves 297 which correspond to the curvature of turnbuckles 250 and 270. Inner surface 209 (FIG. 27) of engaging plate 204 and the inner surface of engaging plate 202 (not readily visible in FIG. 27) also may include arcuate grooves 228 and 240 (FIG. 27), respectively, which correspond to the curvature of turnbuckles 270 and 250.

Returning to FIG. 28, first threaded portion 252 of first turnbuckle 250 is preferably threaded in a first direction and second threaded portion 254 of first turnbuckle 250 is preferably threaded in a direction opposite the first direction. First threaded portion 272 of second turnbuckle 270 is preferably threaded in a second direction and second threaded portion 274 of second turnbuckle 270 is preferably threaded in a direction opposite the second direction. First threaded portions 252 and 272 may be threaded in the same direction or in opposite directions. First turnbuckle 250 is preferably configured to be coupled to cam blocks 260 and 261; second turnbuckle 270 is preferably configured to be coupled to cam blocks 280 and 281. Cam block 260 is preferably coupled to first turnbuckle 250 through opening 266 (FIG. 29B). Opening 266 is preferably threaded complementarily to first portion 252 of first turnbuckle 250. Cam blocks 261, 280, and 281 are preferably similarly configured for coupling to turnbuckle portions 254, 272, and 274, respectively.

Cam block 260 preferably includes upper surface 262 having a first slope and lower surface 264 having a second slope (FIG. 29C); cam blocks 261, 280, and 281 are preferably similarly configured. The slopes of corresponding features on paired cam blocks (e.g., the slopes of upper surface 262 of cam block 260 and upper surface 263 of cam block 261) are preferably equivalent. Alternatively, the slopes of corresponding features on paired cam blocks may differ. In addition, the slope of upper surface 262 of cam block 260 need not be equivalent to the slope of lower surface 264 of cam block 260. Further, the slope of upper surface 262 of cam block 260 need not be equivalent to the slope of upper surface 282 of cam block 280, to the slope of upper surface 283 of cam block 281, or to the slopes of the lower surfaces of cam blocks 280 and 281 (not visible in FIG. 28).

Referring to FIG. 27, inner surface 209 of engaging plate 204 preferably includes sloped tracks 220, 222, 224, and 226. Sloped tracks 220, 222, 224, and 226 are preferably constructed such that the slopes of sloped tracks 220, 222, 224, and 226 are substantially equivalent to the slopes of lower surface 264 of cam

block 260 and to the lower surfaces of cam blocks 261, 280, and 281, respectively. The inner surface of engaging plate 202 also preferably includes sloped tracks 230, 232, 234, and 236 (the ends of which are visible in FIG. 27). Sloped tracks 230, 232, 234, and 236 are preferably constructed such that the slopes of sloped tracks 230, 232, 234, and 236 are substantially equivalent to the slopes of upper surfaces 262, 263, 282, and 283 (FIG. 28), respectively, of cam blocks 260, 261, 280, and 281.

Referring to FIG. 28, turnbuckles 250 and 270 may still further include indentations 258 and 278. Indentations 258 and 278 may be configured to receive the tip of an adjusting tool (not shown). The adjusting tool may be a screwdriver. In a preferred embodiment, the adjusting tool is an allen wrench. The adjusting tool may be used to rotate the furnbuckles. Rotation of first turnbuckle 250 in a first angular direction (e.g., clockwise or counterclockwise) may cause cam blocks 260 and 261 to move away from each other; rotation of first turnbuckle 250 in an angular direction opposite the first angular direction may cause cam blocks 260 and 261 to move toward each other. Rotation of second turnbuckle 270 in a second angular direction may cause cam blocks 280 and 281 to move away from each other; rotation of second turnbuckle 270 in an angular direction opposite the second angular direction may cause cam blocks 280 and 281 to move toward each other. The second angular direction may be the same as the first angular direction: alternatively, the second angular direction may be opposite the first angular direction. Lateral motion of the turnbuckles is preferably inhibited with respect to the bracket assembly. As shown in FIGs. 25-28, rotation of a turnbuckle in a first direction will cause cam blocks coupled to the turnbuckle and having threading complementary to the threading of the turnbuckle to move. Because the ends of the turnbuckle are threaded in opposite directions, the cam blocks will move laterally in opposite directions.

As depicted in FIGs. 25-28, the cam blocks and sloped tracks are preferably constructed such that motion of the cam blocks toward the edges of the engaging plates causes the height between the engaging plates to increase. FIGs. 30A and 30B depict a cutaway view of interbody fusion device 200 in a lowered position and a raised position, respectively. Sloped tracks 230, 232, 220, and 222 correspond to the slopes of cam block surfaces 262, 263, 264, and 265, respectively. In order for the cam blocks to move laterally toward the exterior of the fusion device, as shown in FIGs. 30A and 30B, the interior separation between engaging plates 202 and 204 must be increased to accommodate the height of the cam blocks. Increasing the interior separation in turn increases the exterior height 290 between exterior surfaces 203 of the engaging plates. Rotation of turnbuckle 250 in a first direction causes lateral motion of cam blocks 260 and 261 toward the exterior of interbody fusion device 200. Because the slopes of surfaces 262, 263, 264, and 265 of the cam blocks match the slopes of sloped tracks 230, 232, 220, and 222, the lateral motion of the cam blocks forces engaging plates 202 and 204 apart and increases height 290. Rotation of turnbuckle 250 in a direction opposite the first direction will cause the cam blocks to move toward the interior of the fusion device, decreasing height 290.

The cam blocks and sloped tracks, however, may be constructed such that motion of the cam blocks away from the edges of the engaging plates causes the height between the engaging plates to increase, as depicted in FIGs. 31A and 31B. Features of the interbody fusion device are labeled with the suffix "A" in FIGs. 31A and 31B to denote the alternate configuration (e.g., cam block 260A is similar to cam block 260

except for the orientation). As depicted in FIGs. 31A and 31B, rotation of turnbuckle 250A in a first direction causes lateral motion of cam blocks 260A and 261A toward the interior of interbody fusion device 200A. Because the slopes of surfaces 262A, 263A, 264A, and 265A of the cam blocks match the slopes of sloped tracks 230A, 232A, 220A, and 222A, the lateral motion of the cam blocks forces engaging plates 202A and 204A apart, increasing exterior height 290A between surfaces 203A of the engaging plates. Rotation of turnbuckle 250A in a direction opposite the first direction will cause the cam blocks to move toward the exterior of the fusion device, decreasing height 290A.

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FIG. 32A is a top view of fusion device 200 as inserted between two vertebrae (shown in phantom). Anterior edge 208, posterior edge 210, first side edge 212, and second side edge 214 are indicated in FIG. 32A. FIG. 32B is a front (anterior) view of alignment device 200 in a lowered position. Height 290 (the separation between the outer surfaces of engaging plates 202 and 204 at a location lying on first side edge 212 a specified distance from anterior edge 208) and height 292 (the separation between the outer surfaces of engaging plates 202 and 204 at a location lying on second side edge 214 the same specified distance from anterior edge 208) are substantially equivalent when alignment device 200 is in the lowered position as pictured. First turnbuckle 250 and second turnbuckle 270 may be rotated independently of one another to independently adjust heights 290 and 292 to correct a lateral deviation of the spine, as depicted in FIG. 32C. Heights 290 and 292 may be substantially uniform between anterior edge 208 and posterior edge 210 [e.g., when the slopes of upper surfaces 262 and 263 of cam blocks 260 and 261 (FIG. 28) are substantially equivalent]. Alternatively, heights 290 and 292 may be substantially different proximate anterior edge 208 than proximate posterior edge 210 to maintain a substantially natural lordosis of the spine (e.g., when the slope of surface 262 is substantially different from the slope of surface 263).

Referring to FIG. 32C, bone graft material 294 may be packed between engaging plates 202 and 204. A removable endcap (not shown) similar to endcap 25 (FIG. 4B) may be positioned proximate anterior edge 208 to contain bone graft material 294 within the fusion device and to prevent migration of the bone graft outside the engaging plates. The removable endcap may contain one or more openings for allowing bone ingrowth between a vertebral body and bone graft contained between the engaging plates. The removable endcap is preferably made of a plastic material such as polyethylene that tends to be non-irritating and non-abrasive to the surrounding tissues.

To install the fusion device, a discectomy is preferably performed from an anterior approach. All cartilage and soft tissue are preferably removed from the vertebral endplate as would normally be done for placement of a femoral strut graft. Such a procedure is well within the knowledge of a skilled practitioner of the art. The engaging plates may be deployed in the disc space between the adjacent vertebrae. Turnbuckles 250 and 270 may be rotated to achieve the desired heights 290 and 292 between outer surfaces 203 of engaging plates 202 and 204 at first side edge 212 and second side edge 214. The proper heights may be determined beforehand using x-ray techniques in which the side portions of the intervertebral disc space are examined.

FIG. 33 is an exploded view of an alternate embodiment of an interbody fusion device. Interbody fusion device 300 preferably includes engaging plates 302 and 304 and bracket assembly 306. Engaging

plates 302 and 304 and bracket assembly 306 may be formed of titanium, stainless steel, polymer, ceramic, composite material, or any other biocompatible material. Engaging plates 302 and 304 may include protrusions 316 and openings 318. Bracket assembly 306 is depicted in perspective view in FIG. 34. First turnbuckle 350 and second turnbuckle 370 are preferably positioned substantially parallel to and substantially adjacent anterior edge 308 and posterior edge 310, respectively, of interbody fusion device 300 and extend between first side edge 312 and second side edge 314.

Interbody fusion device 300 as depicted is similar to interbody fusion device 200 depicted in FIGs. 25-28 except for the orientation of the adjusting mechanism. Thus, first turnbuckle 350 is preferably coupled to cam blocks 360 and 361 at first and second threaded portions 352 and 354, respectively; second turnbuckle 370 is preferably coupled to cam blocks 380 and 381 at first and second threaded portions 372 and 374, respectively (FIG. 34). Cam blocks 360 and 361 may contact engaging plate 302 in sloped tracks 330 and 332, respectively (the ends of which are visible in FIG. 33); cam blocks 360 and 361 may contact engaging plate 304 in sloped track 320 and in a sloped track (not visible) similar to sloped track 320, respectively. Cam blocks 380 and 381 may contact engaging plate 302 in sloped tracks 334 and 336, respectively (the ends of which are visible in FIG. 33): cam blocks 380 and 381 may contact engaging plate 304 in sloped tracks 324 and 326, respectively. Inner surface 309 (FIG. 33) of engaging plate 304 and the inner surface of engaging plate 302 (not readily visible in FIG. 33) also may include arcuate grooves 328 and 340, respectively, which correspond to the curvature of turnbuckles 370 and 350. First turnbuckle 350 may contact bracket assembly 306 at lateral projection 342 and second turnbuckle 370 may contact bracket assembly 306 in arcuate grooves (similar to arcuate grooves 297 in FIG. 29A) in ends 396.

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Adjustment of the height between engaging plates 302 and 304 by rotation of turnbuckles 350 and 370 is preferably similar to the adjustment process by rotation of turnbuckles 250 and 270 as previously described for interbody fusion device 200. Heights between engaging plates 302 and 304 along anterior edge 308 and along posterior edge 310 may be varied substantially independently to maintain a substantially natural lordosis. In addition, slopes of upper and lower surfaces of the cam blocks may be unequal such that heights between engaging plates 302 and 304 along first side edge 312 and second side edge 314 may vary between anterior edge 308 and posterior edge 310 to maintain a substantially natural lateral alignment.

FIG. 35 is an exploded view of interbody fusion device 400, which includes engaging plates 202 and 204 (see FIGs. 25-27) and bracket assembly 406. Engaging plates 202 and 204 and bracket assembly 406 may be formed of titanium, stainless steel, polymer, ceramic, composite material, or any other biocompatible material. FIG. 36 is a perspective view of alternative bracket assembly 406 which may be placed between engaging plates 202 and 204. Lateral projections 442 and 444 of bracket assembly 406 may support screws 450 and 470, respectively. FIG. 37A depicts a cross-sectional view of screw 450. Screw 450 preferably includes threaded portion 452 and unthreaded portion 454. A diameter of threaded portion 452 may be greater than a diameter of unthreaded portion 454. Cam block 460 may include an opening such that inner surface 461 of the opening is substantially unthreaded. Unthreaded portion 454 of screw 450 may then be free to rotate within cam block 460. Cam block 468 may include an opening such that inner surface 469 of the

opening is threaded complementarily to threaded portion 452 of screw 450. Projection 442 of bracket assembly 406 may also include openings with inner surfaces 443 threaded complementarily to threaded portion 452 of screw 450.

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Screw 450 may further include flange 456. A diameter of flange 456 may be substantially greater than a diameter of unthreaded portion 454. Flange 456 may maintain coupling between cam block 460 and unthreaded portion 454 of screw 450. Screw 450 may still further include indentation 458. Indentation 458 may be configured to receive the tip of an adjusting tool (not shown). The adjusting tool may be a screwdriver. In a preferred embodiment, the adjusting tool is an allen wrench. Ends 498 of bracket assembly 406 may include arcuate grooves 499 to allow access of the adjusting tool to indentations 458 and 478 (shown in FIG. 36) of screws 450 and 470, respectively.

Rotation of screw 450 in a first angular direction may cause cam blocks 460 and 468 to move away from each other, as depicted in FIG. 37B. Rotation of screw 450 in an angular direction opposite the first angular direction may cause cam blocks 460 and 468 to move toward one another, as depicted in FIG. 37A. Alternatively, rotation of screw 450 in a first angular direction may cause cam blocks 460 and 468 to move toward each other, and rotation of screw 450 in an angular direction opposite the first angular direction may cause cam blocks 460 and 468 to move away from one another. Screw 470, cam blocks 480 and 488, and lateral projection 444 (FIG. 36) may possess features similar to those of screw 450, cam blocks 460 and 468, and lateral projection 442, respectively.

Heights between engaging plates 402 and 404 along first side edge 412 and along second side edge 414 may be varied substantially independently to maintain a substantially natural lateral alignment. In addition, slopes of upper and lower surfaces of the cam blocks may be unequal such that heights between engaging plates 402 and 404 along anterior edge 408 and posterior edge 410 may vary between first side edge 412 and second side edge 414 to maintain a substantially natural lordosis.

An alternate embodiment of an interbody fusion device is depicted in an exploded view in FIG. 38. Interbody fusion device 500 preferably includes engaging plates 502 and 504 and bracket assembly 506. Engaging plates 502 and 504 and bracket assembly 506 may be formed of titanium, stainless steel, polymer, ceramic, composite material, or any other biocompatible material. Engaging plates 502 and 504 may include protrusions 516 and openings 518. Bracket assembly 506 (depicted in perspective view in FIG. 39) may include an alignment device for changing a height between engaging plates 502 and 504. In an embodiment, the alignment device includes first turnbuckle 540 positioned substantially parallel to and substantially adjacent second side edge 514, second turnbuckle 550 positioned substantially parallel to and substantially adjacent anterior edge 508, and third turnbuckle 560 positioned substantially parallel to and substantially adjacent first side edge 512. Bracket assembly 506 may include lateral projections 584, 586, and 588 extending into the interior of the bracket assembly and supporting turnbuckles 540, 550, and 560, respectively. The turnbuckles may include middle portions (e.g., middle portions 543 and 553 of turnbuckles 540 and 550, respectively) disposed between the ends of the turnbuckles and having a diameter greater than a diameter of the threaded portions. Lateral projections 584, 586, and 588 are preferably sized such that the middle portions are retained within the lateral projections while the turnbuckles are free to rotate within the

lateral projections. Inner surface 509 of engaging plate 504 (FIG. 38) and the inner surface of engaging plate 502 (not readily visible in FIG. 38) may include arcuate grooves 534 and 532, respectively, which correspond to the curvature of turnbuckles 540, 550, and 560.

Returning to FIG. 39, first threaded portion 541 of first turnbuckle 540 may be threaded in a first direction and second threaded portion 542 of first turnbuckle 540 may be threaded in a direction opposite the first direction. First threaded portion 551 of second turnbuckle 550 may be threaded in a second direction and second threaded portion 552 of second turnbuckle 550 may be threaded in a direction opposite the second direction. First threaded portion 561 of third turnbuckle 560 may be threaded in a third direction and second threaded portion 562 of third turnbuckle 560 may be threaded in a direction opposite the third direction. First threaded portions 541, 551, and 561 may be threaded in the same direction; alternatively, one of the first threaded portions may be threaded in a direction opposite the direction of the other two first threaded portions.

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First turnbuckle 540 is preferably configured to be coupled to cam blocks 544 and 545. Second turnbuckle 550 is preferably configured to be coupled to cam blocks 554 and 555. Third turnbuckle 560 is preferably configured to be coupled to cam blocks 564 and 565. The cam blocks are preferably coupled to the turnbuckles as depicted for cam block 260 and turnbuckle 250 (FIG. 29B). The surfaces of cam blocks 544, 545, 555, 564, and 565 are preferably sloped as previously described for cam block 260 (FIG. 29C).

Inner surface 509 of engaging plate 504 preferably includes sloped tracks (e.g., 520, 521, 522, 524, and 525 visible in FIG. 38) configured to correspond to the lower surfaces of cam blocks 544, 545, 554, 555, 564, and 565, respectively. The inner surface of engaging plate 502 preferably also includes sloped tracks 526, 527, 528, 529, 530, and 531 (the ends of which are visible in FIG. 38) configured to correspond to the upper surfaces of cam blocks 544, 545, 554, 555, 564, and 565, respectively.

Turnbuckles 540, 550, and 560 may still further include indentations (indentation 558 of second turnbuckle 550 is visible in FIG. 39). The indentations may be configured to receive the tip of an adjusting tool (not shown). The adjusting tool may be a screwdriver. In a preferred embodiment, the adjusting tool is an allen wrench. Bracket assembly 506 preferably contains fenestrations 590 and 592 to facilitate access of the adjusting tool to the indentations. The adjusting tool may be used to rotate the turnbuckles. Rotation of first turnbuckle 540 in a first angular direction may cause cam blocks 544 and 545 to move away from each other: rotation of first turnbuckle 540 in an angular direction opposite the first angular direction may cause cam blocks 544 and 545 to move toward each other. Rotation of second turnbuckle 550 in a second angular direction may cause cam blocks 554 and 555 to move away from each other; rotation of second turnbuckle 550 in an angular direction opposite the second angular direction may cause cam blocks 554 and 555 to move toward each other. Rotation of third turnbuckle 560 in a third angular direction may cause cam blocks 564 and 565 to move away from each other; rotation of third turnbuckle 560 in an angular direction opposite the third angular direction may cause cam blocks 564 and 565 to move away from each other. The first, second, and third angular directions may be the same; alternatively, one of the angular directions may be opposite the other two angular directions.

As depicted in FIGs. 38-39, cam blocks 544, 545, 554, 555, 564 and 565 and sloped tracks 520-531 may be configured such that motion of the cam blocks toward the edges of the engaging plates causes the

height between the engaging plates to increase. The cam blocks and sloped tracks, however, may be configured such that motion of the cam blocks away from the edges of the engaging plates causes the height between the engaging plates to increase.

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The turnbuckles in fusion device 500 may be positioned such that heights between engaging plates 502 and 504 along first side edge 512 and along second side edge 514 may be varied substantially independently to maintain a substantially natural lateral alignment. The turnbuckles in fusion device 500 may also be positioned such that heights between engaging plates 502 and 504 along anterior edge 508 and posterior edge 510 be varied substantially independently to maintain a substantially natural lordosis. In addition, slopes of upper and lower surfaces of the cam blocks may be unequal such that heights between engaging plates 502 and 504 along first side edge 512 and second side edge 514 may vary between anterior edge 508 and posterior edge 510 to maintain a substantially natural lateral alignment and such that heights between engaging plates 502 and 504 along anterior edge 508 and posterior edge 510 may vary between first side edge 512 and second side edge 514 to maintain a substantially natural lordosis.

An alternate embodiment of an interbody fusion device is depicted in an exploded view in FIG. 40. Interbody fusion device 600 preferably includes engaging plates 602 and 604 and bracket assembly 606. Engaging plates 602 and 604 and bracket assembly 606 may be formed of titanium, stainless steel, polymer, ceramic, composite material, or any other biocompatible material. Engaging plates 602 and 604 may include protrusions 616 and openings 618. Bracket assembly 606 (depicted in perspective view in FIG. 41) preferably includes an alignment device for changing a height between engaging plates 602 and 604. In an embodiment, the alignment device includes first screw 640 positioned substantially parallel to and substantially adjacent second side edge 614; second screw 650 positioned substantially parallel to and substantially centered between first side edge 612 and second side edge 614; and third screw 660 positioned substantially parallel to and substantially adjacent first side edge 612. Inner surfaces 609 of engaging plate 604 (FIG. 40) and the inner surface of engaging plate 602 (not readily visible in FIG. 40) include arcuate grooves 634 and 632, respectively, which correspond to the curvature of screws 640, 650, and 660. Bracket assembly 606 may include support portion 607 (FIG. 41) to support the ends of the screws. Support portion 607 may include arcuate grooves (not readily visible) corresponding to the curvature of screws 640, 650, and 660.

Threaded portion 641 of first screw 640 is preferably threaded in a first direction. Threaded portion 651 of second screw 650 is preferably threaded in a second direction. Threaded portion 661 of third screw 660 is preferably threaded in a third direction. Threaded portions 641, 651, and 661 may be threaded in the same direction; alternatively, one of the threaded portions may be threaded in a direction opposite the direction of the other two threaded portions.

First screw 640 is preferably coupled to cam block 644. Second screw 650 is preferably coupled to cam block 654. Third screw 660 is preferably coupled to cam block 664. Cam blocks 644, 654, and 664 preferably differ from the cam blocks of previously described embodiments substantially only in shape. Thus, cam blocks 644, 654, and 664 are preferably coupled to screws 640, 650, and 6600 in a manner similar to that depicted for cam block 260 and turnbuckle 250 (FIG. 29B). Cam blocks 644, 654, and 664 preferably include

sloped upper and lower surfaces similar to the sloped upper and lower surfaces as previously described for cam blocks in other embodiments.

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Inner surface 609 of engaging plate 604 preferably includes sloped tracks 620 and 621 corresponding to the slopes of the lower surfaces of cam block 644, sloped tracks 622 and 623 corresponding to the slopes of the lower surfaces of cam block 654, and sloped tracks 624 and 625 corresponding to the slopes of the lower surfaces of cam block 664. The inner surface of engaging plate 602 also preferably includes sloped tracks (the ends of which are visible in FIG. 40). Sloped tracks 626 and 627 preferably correspond to the slope of the upper surfaces of cam block 644. Sloped tracks 628 and 629 preferably correspond to the slope of the upper surfaces of cam block 654. Sloped tracks 630 and 631 preferably correspond to the slope of the upper surfaces of cam block 664.

Screws 640, 650, and 660 may still further include indentations 648; 658, and 668 (FIG. 41). The indentations may be configured to receive the tip of an adjusting tool (not shown). The adjusting tool may be a screwdriver. In a preferred embodiment, the adjusting tool is an allen wrench. Rotation of first screw 640 in a first angular direction may cause cam block 644 to move toward anterior edge 608; rotation of first screw 640 in an angular direction opposite the first angular direction may cause cam block 644 to move toward posterior edge 610. Rotation of second screw 650 in a second angular direction may cause cam block 654 to move toward anterior edge 608; rotation of second screw 650 in an angular direction opposite the second angular direction may cause cam block 654 to move toward posterior edge 610. Rotation of third screw 660 in a third angular direction may cause cam block 664 to move toward anterior edge 608; rotation of third screw 660 in an angular direction opposite the third angular direction may cause cam block 664 to move toward posterior edge 610. The first, second, and third angular directions may be the same; alternatively, one of the first, second, and third angular directions may be opposite the other two of the first, second, and third angular directions.

As depicted in FIGs. 40-41, the cam blocks and sloped tracks are preferably configured such that motion of the cam blocks toward the edges of the engaging plates causes the height between the engaging plates to increase. The cam blocks and sloped tracks, however, may be configured such that motion of the cam blocks away from the edges of the engaging plates causes the height between the engaging plates to increase.

The screws in fusion device 600 may be positioned such that heights between engaging plates 602 and 604 along first side edge 612 and along second side edge 614 may be varied substantially independently to maintain a substantially natural lateral alignment. The screws in fusion device 600 may also be positioned such that heights between engaging plates 602 and 604 along anterior edge 608 and posterior edge 610 may be varied substantially independently to maintain a substantially natural lordosis. In addition, slopes of upper and lower surfaces of the cam blocks may be unequal such that heights between engaging plates 602 and 604 along first side edge 612 and second side edge 614 may vary between anterior edge 608 and posterior edge 610 to maintain a substantially natural lateral alignment and such that heights between engaging plates 602 and 604 along anterior edge 608 and posterior edge 610 may vary between first side edge 612 and second side edge 614 to maintain a substantially natural lordosis.

An alternate embodiment of an interbody fusion device is depicted in an exploded view in FIG. 42. Interbody fusion device 700 preferably includes engaging plates 702 and 704 and bracket assembly 706. Engaging plates 702 and 704 and bracket assembly 706 may be formed of titanium, stainless steel, polymer, ceramic, composite material, or any other biocompatible material. Engaging plates 702 and 704 may include protrusions 716 and openings 718. Bracket assembly 706 (depicted in perspective view in FIG. 43A) preferably includes an alignment device for changing a height between engaging plates 702 and 704. In an embodiment, the alignment device includes first screw 740, positioned substantially parallel to and substantially centered between first side edge 712 and second side edge 714; second screw 750 positioned at a first angle Φ (FIG. 42) with respect to first screw 740; and third screw 760 positioned at a second angle Θ to first screw 740. In the embodiment pictured in FIGs. 42 and 43A,  $\Phi = 90^{\circ}$  and  $\Theta = 90^{\circ}$ , such that second screw 750 and third screw 760 are preferably positioned substantially parallel to and substantially centered between anterior edge 708 and posterior edge 710 (FIG. 43A) and such that second screw 750 and third screw 760 preferably share a common axis of rotation. The alignment device further includes stationary block 790 to maintain the spatial relationship between screws 740, 750, and 760. In an alternate embodiment,  $\Phi = 90^{\circ}$ and  $\Theta > 90^{\circ}$ . In a further alternate embodiment,  $\Phi > 90^{\circ}$  and  $\Theta = 90^{\circ}$ . In a further alternate embodiment still.  $\Phi > 90^{\circ}$  and  $\Theta > 90^{\circ}$ . In another embodiment, first screw 740 may be positioned other than parallel to and centered between opposite edges of the fusion device, screws 750 and 760 being positioned at angles  $\Phi$  and Θ, respectively, with respect to first screw 740.

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The inner surfaces of engaging plates 702 and 704 preferably include arcuate grooves 732 and 734 (FIG. 42), respectively, which correspond to the curvature of screws 740, 750, and 760. Bracket assembly 706 preferably includes support portions 707 (FIG. 43A) to support the ends of the screws. Support portions 707 preferably include arcuate grooves (not readily visible in FIGs. 42 and 43A) corresponding to the curvature of screws 740, 750, and 760.

Threaded portion 741 of first screw 740 preferably is threaded in a first direction. Threaded portion 751 of second screw 750 preferably is threaded in a second direction. Threaded portion 761 of third screw 760 preferably is threaded in a third direction. Threaded portions 741, 751, and 761 may be threaded in the same direction; alternatively, one of the threaded portions may be threaded in a direction opposite the direction of the threading of the other two threaded portions. Screws 740, 750, and 760 may also include unthreaded portions (e.g., unthreaded portion 762 visible in FIG. 43A). FIG. 43B shows a detail of screw 740 including unthreaded portion 742. Unthreaded portion 742 may be inserted into cavity 792 (shown in phantom) in stationary block 790. Screw 740 thus may be free to rotate within stationary block 790. Stationary block 790 may be configured to be similarly coupled to screws 750 and 760. Engagement between stationary block 790 and screws 740, 750, and 760 preferably maintains coupling between screws 740, 750, and 760 and cam blocks 744, 754, and 764, respectively (that is, stationary block 790 preferably serves to stop motion of the cam blocks toward the interior of the fusion device such that the cam blocks are not separated from the screws). Stationary block 790 is pictured as a cube; however, stationary block 790 be of virtually any shape (e.g., cylinder, sphere, "T" shape similar to the positioning of screws 740, 750, and 760 that will maintain coupling between the screws and the cam blocks. Cam blocks 744, 754, and 764 are preferably

coupled to screws 740, 750, and 760 in a manner similar to that depicted for cam block 236 and turnbuckle 226 (FIG. 29B). Cam blocks 744, 754, and 764 preferably include sloped upper and lower surfaces similar to the sloped upper and lower surfaces as previously described for cam blocks in other embodiments.

Returning to FIG. 42, inner surface 709 of engaging plate 704 preferably includes sloped tracks 720, 722, and 724 configured to correspond to the lower surfaces of cam blocks 744, 754, and 764, respectively. The inner surface of engaging plate 702 (not readily visible) also preferably includes sloped tracks 726, 728 and 730 (the ends of which are visible in FIG. 42). Sloped tracks 726, 728, and 730 are preferably configured to correspond to the upper surfaces of cam blocks 744, 754, and 764, respectively.

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Screws 740, 750, and 760 may still further include indentations (e.g., indentations 748 and 758, visible in FIG. 43A). The indentations may be configured to receive the tip of an adjusting tool (not shown). The adjusting tool may be a screwdriver. In a preferred embodiment, the adjusting tool is an allen wrench. Rotation of first screw 740 in a first angular direction may cause cam block 744 to move toward anterior edge 708; rotation of first screw 740 in an angular direction opposite the first angular direction may cause cam block 744 to move away from anterior edge 708. Rotation of second screw 750 in a second angular direction may cause cam block 754 to move toward second side edge 714; rotation of second screw 750 in an angular direction opposite the second angular direction may cause cam block 754 to move away from second side edge 714. Rotation of third screw 760 in a third angular direction may cause cam block 764 to move toward first side edge 712; rotation of third screw 760 in an angular direction opposite the third angular direction may cause cam block 764 to move away from first side edge 712. The first, second, and third angular directions may be the same; alternatively, one of the first, second, and third angular directions may be opposite the other two angular directions.

Sloped tracks 720, 722, and 724 in lower engaging plate 704 and sloped tracks 726, 728, and 730 in upper engaging plate 702 are preferably configured to guide the motion of the cam blocks as the screws are rotated. As depicted in FIGs. 42 and 43A, the cam blocks and sloped tracks may be configured such that motion of the cam blocks toward the edges of the engaging plates causes the height between the engaging plates to increase. The cam blocks and sloped tracks, however, may be configured such that motion of the cam blocks away from the edges of the engaging plates causes the height between the engaging plates to increase.

The screws in fusion device 700 may be positioned such that heights between engaging plates 702 and 704 along first side edge 712 and along second side edge 714 may be varied substantially independently to maintain a substantially natural lateral alignment. The screws in fusion device 700 may also be positioned such that heights between engaging plates 702 and 704 along anterior edge 708 and posterior edge 710 be varied substantially independently to maintain a substantially natural lordosis. In addition, slopes of upper and lower surfaces of the cam blocks may be unequal such that heights between engaging plates 702 and 704 along first side edge 712 and second side edge 714 may vary between anterior edge 708 and posterior edge 710 to maintain a substantially natural lateral alignment and such that heights between engaging plates 702 and 704 along anterior edge 708 and posterior edge 710 may vary between first side edge 712 and second side edge 714 to maintain a substantially natural lordosis.

An alternate embodiment of an interbody fusion device including two parallel pairs of screws is depicted in an exploded view in FIG. 44. Interbody fusion device 800 preferably includes engaging plates 802 and 804 and bracket assembly 806. Engaging plates 802 and 804 and bracket assembly 806 may be formed of titanium, stainless steel, polymer, ceramic, composite material, or any other biocompatible material. Engaging plates 802 and 804 may include protrusions 816 and openings 818. Bracket assembly 806 (depicted in perspective view in FIG. 45) preferably includes an alignment device for changing a height between engaging plates 802 and 804. In an embodiment, the alignment device includes first screw 850 and second screw 860 having a common axis of rotation and positioned substantially parallel to and substantially adjacent posterior edge 810 and third screw 870 and fourth screw 880 having a common axis of rotation and positioned substantially parallel to and substantially adjacent anterior edge 808. The inner surfaces of engaging plates 802 and 804 preferably include arcuate grooves 840 and 842 (FIG. 44), respectively, which correspond to the curvature of screws 850, 860, 870, and 880. Bracket assembly 806 may include support portion 807 to support the ends of screws 860 and 880. Support portion 807 may include arcuate grooves corresponding to the curvature of screws 860 and 880 (not readily visible in FIGs. 44 and 45). Bracket assembly 806 preferably further includes ends 898 including arcuate grooves (not readily visible) corresponding to the curvature of screws 850 and 870.

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Threaded portion 851 of first screw 850 may be threaded in a first direction. Threaded portion 861 of second screw 860 may be threaded in a second direction. Threaded portion 871 of third screw 870 may be threaded in a third direction. Threaded portion 881 of fourth screw 880 may be threaded in a fourth direction. Threaded portions 851, 861, 871, and 881 may be threaded in the same direction. Alternatively, one of the threaded portions may be threaded in a direction opposite the direction of the other three threaded portions. Alternatively, two of the threaded portions may be threaded in a direction opposite the direction of the other two threaded portions.

Screws 850, 860, 870, and 880 may include unthreaded portions (e.g., unthreaded portion 862 visible in FIG. 45) similar to unthreaded portion 742 of screw 740 (FIG. 43A). Lateral projections 894 and 896 may include substantially unthreaded openings, similar to unthreaded openings 792 of stationary block 790 (FIG. 43B), adapted to receive the unthreaded portions of the screws and in which the unthreaded portions of the screws are free to rotate.

First screw 851 is preferably configured to be coupled to cam block 854. Second screw 860 is preferably configured to be coupled to cam block 864. Third screw 870 is preferably configured to be coupled to cam block 874. Fourth screw 880 is preferably configured to be coupled to cam block 884. Cam blocks 854, 864, 874, and 884 are preferably coupled to screws 850, 860, 870 and 880 in a manner similar to that depicted for cam block 744 and turnbuckle 740 (FIG. 43B). Cam blocks 850, 860, 870, and 880 preferably include sloped upper and lower surfaces similar to the sloped upper and lower surfaces as previously described for cam blocks in other embodiments.

Returning to FIG. 42, inner surface 809 of engaging plate 804 preferably includes sloped track 820 configured to correspond to the lower surface of cam block 850; a sloped track (not visible) configured to correspond to the lower surface of cam block 860; sloped track 824 configured to correspond to the lower.

surface of cam block 870; and sloped track 826 configured to correspond to the lower surface of cam block 880. The inner surface of engaging plate 802 preferably includes sloped tracks 830, 832, 834, and 836 (the ends of which are visible in FIG. 44). Sloped tracks 830, 832, 834, and 836 are preferably configured to correspond to the upper surfaces of cam blocks 850, 860, 870, and 880, respectively.

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Screws 850, 860, 870, and 880 may still further include indentations (e.g., indentations 858 and 878, visible in FIG. 45). The indentations may be configured to receive the tip of an adjusting tool (not shown). The adjusting tool may be a screwdriver. In a preferred embodiment, the adjusting tool is an allen wrench. Rotation of first screw 850 in a first angular direction may cause cam block 854 to move toward second side edge 814; rotation of first screw 850 in an angular direction opposite the first angular direction may cause cam block 854 to move toward first side edge 812. Rotation of second screw 860 in a second angular direction may cause cam block 864 to move toward first side edge 812; rotation of second screw 860 in an angular direction opposite the second angular direction may cause cam block 864 to move toward second side edge 814. Rotation of third screw 870 in a third angular direction may cause cam block 874 to move toward second side edge 814; rotation of first screw 870 in an angular direction opposite the third angular direction may cause cam block 874 to move toward first side edge 812. Rotation of fourth screw 880 in a fourth angular direction may cause cam block 884 to move toward first side edge 812; rotation of fourth screw 880 in an angular direction opposite the fourth angular direction may cause cam block 884 to move toward second side edge 814. The first, second, third, and fourth angular directions may be the same. Alternatively, one of the first, second, third, and fourth angular directions may be opposite the other three of the first, second, third, and fourth angular directions. Alternatively, two of the first, second, third, and fourth angular directions may be opposite the other two of the first, second, third, and fourth angular directions.

As depicted in FIGs. 44-45, the cam blocks and sloped tracks are preferably configured such that motion of the cam blocks toward the edges of the engaging plates causes the height between the engaging plates to increase. The cam blocks and sloped tracks, however, may be configured such that motion of the cam blocks away from the edges of the engaging plates causes the height between the engaging plates to increase.

The screws in fusion device 800 may be positioned such that heights between engaging plates 802 and 804 along first side edge 812 and along second side edge 814 may be varied substantially independently to maintain a substantially natural lateral alignment. The screws in fusion device 800 may also be positioned such that heights between engaging plates 802 and 804 along anterior edge 808 and posterior edge 810 be varied substantially independently to maintain a substantially natural lordosis. In addition, slopes of upper and lower surfaces of the cam blocks may be unequal such that heights between engaging plates 802 and 804 along first side edge 812 and second side edge 814 may vary between anterior edge 808 and posterior edge 810 to maintain a substantially natural lateral alignment and such that heights between engaging plates 802 and 804 along anterior edge 808 and posterior edge 810 may vary between first side edge 812 and second side edge 814 to maintain a substantially natural lordosis.

An alternate embodiment of an interbody fusion device including four screws oriented in a "+" configuration is depicted in an exploded view in FIG. 46. Interbody fusion device 900 preferably includes

engaging plates 902 and 904 and bracket assembly 906. Engaging plates 902 and 904 and bracket assembly 906 may be formed of titanium, stainless steel, polymer, ceramic, composite material, or any other biocompatible material. Engaging plates 902 and 904 may include protrusions 916 and openings 918. Bracket assembly 906 (depicted in perspective view in FIG. 47) preferably includes an alignment device for changing a height between engaging plates 902 and 904. In an embodiment, the alignment device includes first screw 950 and second screw 960 having a common axis of rotation and positioned substantially parallel to and substantially centered between anterior edge 908 and posterior edge 910 and third screw 970 and fourth screw 980 having a common axis of rotation and positioned substantially parallel to and substantially centered between first side edge 912 and second side edge 914. The inner surfaces of engaging plates 902 and 904 preferably include arcuate grooves 940 and 942 (FIG. 46), respectively, which correspond to the curvature of screws 950, 960, 970, and 980. Bracket assembly 906 preferably includes support portions 907 to support the ends of screws 950, 960, 970, and 980. Support portions 907 may include arcuate grooves (not readily visible in FIGs. 46-47) corresponding to the curvature of screws 950, 960, 970, and 980.

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Returning to FIG. 47, threaded portion 951 of first screw 950 preferably is threaded in a first direction. Threaded portion 961 of second screw 960 preferably is threaded in a second direction. Threaded portion 971 of third screw 970 preferably is threaded in a third direction. Threaded portion 981 of fourth screw 980 preferably is threaded in a fourth direction. Threaded portions 951, 961, 971, and 981 may be threaded in the same direction. Alternatively, one of the threaded portions may be threaded in a direction opposite the direction of the other three threaded portions. Alternatively, two of the threaded portions may be threaded in a direction opposite the direction of the other two threaded portions.

Screws 950, 960, 970, and 980 may include unthreaded portions 952, 962, 972, and 982, similar to unthreaded portion 730 of screw 728 (FIG. 43A). Stationary block 990 may include substantially unthreaded openings, similar to unthreaded openings 792 of stationary block 790 (FIG. 43A), adapted to receive the unthreaded portions of the screws and in which the unthreaded portions of the screws are free to rotate.

First screw 951 preferably is configured to be coupled to cam block 954. Second screw 960 preferably is configured to be coupled to cam block 964. Third screw 970 preferably is configured to be coupled to cam block 974. Fourth screw 980 preferably is configured to be coupled to cam block 984. Cam blocks 954, 964, 974, and 984 may be coupled to screws 950, 960, 970 and 980 in a manner similar to that depicted for cam block 744 and turnbuckle 740 (FIG. 43B). Cam blocks 950, 960, 970, and 980 preferably include sloped upper and lower surfaces similar to the sloped upper and lower surfaces as previously described for cam blocks in other embodiments.

Inner surface 909 of engaging plate 904 preferably includes sloped tracks 920, 922, 924, and 926 configured to correspond to the lower surface of cam blocks 950, 960, 970, and 980, respectively. The inner surface of engaging plate 902 preferably includes sloped tracks 930, 932, 934, and 936 (the ends of which are visible in FIG. 46) configured to correspond to the upper surfaces of cam blocks 950, 960, 970, and 980, respectively.

Screws 950, 960, 970, and 980 may still further include indentations (e.g., indentations 958 and 978, visible in FIG. 47). The indentations may be configured to receive the tip of an adjusting tool (not shown).

The adjusting tool may be a screwdriver. In a preferred embodiment, the adjusting tool is an allen wrench. Rotation of first screw 950 in a first angular direction may cause cam block 954 to move away from stationary block 990; rotation of first screw 950 in an angular direction opposite the first angular direction may cause cam block 954 to move toward stationary block 990. Rotation of second screw 960 in a second angular direction may cause cam block 964 to move away from stationary block 990; rotation of second screw 960 in an angular direction opposite the second angular direction may cause cam block 964 to move toward stationary block 990. Rotation of third screw 970 in a third angular direction may cause cam block 974 to move away from stationary block 990; rotation of third screw 970 in an angular direction opposite the third angular direction may cause cam block 974 to move toward stationary block 990. Rotation of fourth screw 980 in a fourth angular direction may cause cam block 984 to move away from stationary block 990; rotation of second screw 980 in an angular direction opposite the fourth angular direction may cause cam block 984 to move toward stationary block 990. The first, second, third, and fourth angular directions may be the same. Alternatively, one of the first, second, third, and fourth angular directions may be opposite the other three of the first, second, third, and fourth angular directions may be opposite the other two of the first, second, third, and fourth angular directions may be opposite the other two of the first, second, third, and fourth angular directions.

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As depicted in FIGs. 46-47, the cam blocks and sloped tracks are preferably configured such that motion of the cam blocks toward the edges of the engaging plates causes the height between the engaging plates to increase. The cam blocks and sloped tracks, however, may be configured such that motion of the cam blocks away from the edges of the engaging plates causes the height between the engaging plates to increase.

The screws in fusion device 900 may be positioned such that heights between engaging plates 902 and 904 along first side edge 912 and along second side edge 914 may be varied substantially independently to maintain a substantially natural lateral alignment. The screws in fusion device 900 may also be positioned such that heights between engaging plates 902 and 904 along anterior edge 908 and posterior edge 910 be varied substantially independently to maintain a substantially natural lordosis. In addition, slopes of upper and lower surfaces of the cam blocks may be unequal such that heights between engaging plates 902 and 904 along first side edge 912 and second side edge 914 may vary between anterior edge 908 and posterior edge 910 to maintain a substantially natural lateral alignment and such that heights between engaging plates 902 and 904 along anterior edge 908 and posterior edge 910 may vary between first side edge 912 and second side edge 914 to maintain a substantially natural lordosis.

An alternate embodiment of an interbody fusion device including four screws oriented in an "x" configuration is depicted in an exploded view in FIG. 48. Interbody fusion device 1000 preferably includes engaging plates 1002 and 1004 and bracket assembly 1006. Engaging plates 1002 and 1004 and bracket assembly 1006 may be formed of titanium, stainless steel, polymer, ceramic, composite material, or any other biocompatible material. Engaging plates 1002 and 1004 may include protrusions 1016 and openings 1018. Bracket assembly 1006 (depicted in perspective view in FIG. 49) preferably includes an alignment device for changing a height between engaging plates 1002 and 1004. In an embodiment, the alignment device includes first screw 1050 and second screw 1060 having a common axis of rotation and positioned substantially along

a diagonal connecting corner 1001 and corner 1005 of bracket assembly 1006. Preferably, bracket assembly 1006 further includes third screw 1070 and fourth screw 1080 having a common axis of rotation and positioned substantially along a diagonal connecting corner 1003 and corner 1007 of bracket assembly 1006. Inner surface 1009 of engaging plate 1004 (FIG. 48) and the inner surface of engaging plate 1002 (not readily visible in FIG. 48) preferably include arcuate grooves 1042 and 1040, respectively, which correspond to the curvature of screws 1050, 1060, 1070, and 1080. Bracket assembly 1006 preferably includes support portions 1098(FIG. 49) to support the ends of screws 1050, 1060, 1070, and 1080. Support portions 1098 preferably include arcuate grooves (not readily visible) corresponding to the curvature of screws 1050, 1060, 1070, and 1080.

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Threaded portion 1051 of first screw 1050 preferably is threaded in a first direction. Threaded portion 1061 of second screw 1060 preferably is threaded in a second direction. Threaded portion 1071 of third screw 1070 preferably is threaded in a third direction. Threaded portion 1081 of fourth screw 1080 preferably is threaded in a fourth direction. Threaded portions 1051, 1061, 1071, and 1081 may be threaded in the same direction. Alternatively, one of the threaded portions may be threaded in a direction opposite the direction of the other three threaded portions. Alternatively, two of the threaded portions may be threaded in a direction opposite the direction of the other two threaded portions.

Screws 1050, 1060, 1070, and 1080 may include unthreaded portions 1052, 1062, 1072, and 1082, similar to unthreaded portion 730 of screw 728 (FIG. 43A). Stationary block 1090 may include substantially unthreaded openings, similar to unthreaded openings 792 of stationary block 790 (FIG. 43B), adapted to receive the unthreaded portions of the screws and in which the unthreaded portions of the screws are free to rotate.

First screw 1051 is preferably configured to be coupled to cam block 1054. Second screw 1060 is preferably configured to be coupled to cam block 1064. Third screw 1070 is preferably configured to be coupled to cam block 1074. Fourth screw 1080 is preferably configured to be coupled to cam block 1084. Cam blocks 1054, 1064. 1074, and 1084 are preferably coupled to screws 1050, 1060, 1070 and 1080 in a manner similar to that depicted for cam block 744 and turnbuckle 740 (FIG. 43B). Cam blocks 1050, 1060, 1070, and 1080 preferably include sloped upper and lower surfaces similar to the sloped upper and lower surfaces as previously described for cam blocks in other embodiments.

Returning to FIG. 48, inner surface 1011 of engaging plate 1004 preferably includes sloped track 1020 configured to correspond to the lower surface of cam block 1050; sloped track 1022 configured to correspond to the lower surface of cam block 1060; sloped track 1024 configured to correspond to the lower surface of cam block 1070; and sloped track 1026 configured to correspond to the lower surface of cam block 1080. The inner surface (not readily visible) of engaging plate 1002 preferably includes sloped tracks 1030, 1032, 1034, and 1036 (the ends of which are visible in FIG. 48) configured to correspond to the upper surfaces of cam blocks 1050, 1060, 1070, and 1080, respectively.

Screws 1050, 1060, 1070, and 1080 may still further include indentations (e.g., indentation 1058, visible in FIG. 49). The indentations may be configured to receive the tip of an adjusting tool (not shown). The adjusting tool may be a screwdriver. In a preferred embodiment, the adjusting tool is an allen wrench.

Rotation of first screw 1050 in a first angular direction may cause cam block 1054 to move away from stationary block 1090; rotation of first screw 1050 in an angular direction opposite the first angular direction may cause cam block 1054 to move toward stationary block 1090. Rotation of second screw 1060 in a second angular direction may cause cam block 1064 to move away from stationary block 1090; rotation of second screw 1060 in an angular direction opposite the second angular direction may cause cam block 1064 to move toward stationary block 1090. Rotation of third screw 1070 in a third angular direction may cause cam block 1074 to move away from stationary block 1090; rotation of third screw 1070 in an angular direction opposite the third angular direction may cause cam block 1074 to move toward stationary block 1090. Rotation of fourth screw 1080 in a fourth angular direction may cause cam block 1084 to move away from stationary block 1090; rotation of second screw 1080 in an angular direction opposite the fourth angular direction may cause cam block 1084 to move toward stationary block 1090. The first, second, third, and fourth angular directions may be opposite the other three of the first, second, third, and fourth angular directions may be opposite the other three of the first, second, third, and fourth angular directions. Alternatively, two of the first, second, third, and fourth angular directions may be opposite the other two of the first, second, third, and fourth angular directions.

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As depicted in FIGs. 48-49, the cam blocks and sloped tracks may be configured such that motion of the cam blocks toward the edges of the engaging plates causes the height between the engaging plates to increase. The cam blocks and sloped tracks, however, may be configured such that motion of the cam blocks away from the edges of the engaging plates causes the height between the engaging plates to increase.

The screws in fusion device 1000 may be positioned such that heights between engaging plates 1002 and 1004 along first side edge 1012 and along second side edge 1014 may be varied substantially independently to maintain a substantially natural lateral alignment. The screws in fusion device 1000 may also be positioned such that heights between engaging plates 1002 and 1004 along anterior edge 1008 and posterior edge 1010 be varied substantially independently to maintain a substantially natural lordosis. In addition, slopes of upper and lower surfaces of the cam blocks may be unequal such that heights between engaging plates 1002 and 1004 along first side edge 1012 and second side edge 1014 may vary between anterior edge 1008 and posterior edge 1010 to maintain a substantially natural lateral alignment and such that heights between engaging plates 1002 and 1004 along anterior edge 1008 and posterior edge 1010 may vary between first side edge 1012 and second side edge 1014 to maintain a substantially natural lordosis.

An alternate embodiment of an interbody fusion device is depicted in FIGs. 50-52. FIG. 50A depicts interbody fusion device 1100 in a lowered position. FIG. 50B depicts interbody fusion device 1100 in a raised position. FIG. 50C depicts interbody fusion device 1100 in an exploded view. Interbody fusion device 1100 preferably includes engaging plates 1102 and 1104 supported by bracket assembly 1106 (FIGs. 50A-50C). Engaging plates 1102 and 1104 and bracket assembly 1106 may be formed of titanium, stainless steel, polymer, ceramic, composite material, or any other biocompatible material. Engaging plates 1102 and 1104 may include protrusions 1116. Bracket assembly 1106 may include an alignment device for changing a height between engaging plates 1102 and 1104. In an embodiment, the alignment device includes turnbuckle 1140 positioned between and substantially parallel to first elongated edge 1112 and second elongated edge 1114.

Bracket assembly 1106 may include lateral projection 1124 extending into the interior of the bracket assembly and supporting turnbuckle 1140. Turnbuckle 1140 may include middle portion 1146 (FIG. 51A), similar to middle portion 543 of turnbuckle 540 (FIG. 38), disposed between the ends of the turnbuckle and having a diameter greater than a diameter of the threaded portions. Lateral projection 1124 (FIG. 50C) is preferably sized such that middle portion 1146 of turnbuckle 1140 is retained within the lateral projection while the turnbuckle is free to rotate within the lateral projection. Inner surface 1109 of engaging plate 1104 (FIG. 50C) and the inner surface of engaging plate 1102 (not readily visible in FIG. 50C) may include arcuate grooves 1128 and 1126, respectively, which correspond to the curvature of turnbuckle 1140.

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Turning to FIG. 51A, first threaded portion 1142 of turnbuckle 1140 may be threaded in a first direction and second threaded portion 1144 may be threaded in a direction opposite the first direction. Turnbuckle 1140 is preferably configured to be coupled to cam blocks 1150 and 1160. Cam blocks 1150 and 1160 are preferably similar to cam block 260 in FIG. 29B. The cam blocks are preferably coupled to the turnbuckle as depicted for cam block 260 and turnbuckle 250 (FIG. 29B). The slopes of corresponding features (e.g., upper surfaces) on the cam blocks may be substantially equivalent. Alternatively, the slopes of corresponding features on the paired cam blocks may be different. Further, the slopes of the upper and lower surfaces on an individual cam block may differ.

In another embodiment (not shown), bracket assembly 1106 may include a turnbuckle and cam blocks similar to turnbuckle 450 and cam blocks 460 and 468 of interbody fusion device 400 (FIGs. 36-37). In still another embodiment (not shown), bracket assembly 1106 may include a screw and a cam block similar to screw 650 and cam block of 654 interbody fusion device 600 (FIG. 40). In yet another embodiment (not shown), bracket assembly 1106 may include a screw similar to screw 650 threaded through a cam block similar to cam block 460.

Referring to FIG. 50C, inner surface 1109 of engaging plate 1104 preferably includes sloped tracks 1130 and 1132 constructed such that the slopes of the sloped tracks are substantially equivalent to the slopes of the lower surfaces of cam blocks 1150 and 1160, respectively. The inner surface of engaging plate 1102 preferably includes sloped tracks 1134 and 1136, the ends of which are visible in FIG. 50C, constructed such that the slopes of the sloped tracks are substantially equivalent to the slopes of the upper surfaces of cam blocks 1150 and 1160, respectively.

As depicted in FIGs. 50A-50C, bracket assembly 1106 encloses openings at first narrow edge 1108 and second narrow edge 1110. FIG. 51A is a cut-away perspective view of bracket assembly 1106; FIG. 51B is a cross-sectional view of bracket assembly 1106. Openings 1120 and 1122 (FIG. 51B) may be sized such that bracket assembly 1106 substantially surrounds the ends of turnbuckle 1140 and such that turnbuckle 1140 is free to rotate within the openings. In an alternate embodiment (FIGs. 51C and 51D), bracket assembly 1106A encloses openings only at one of the narrow edges. Opening 1120A may be sized such that bracket assembly 1106A substantially surrounds the end of turnbuckle 1140A and such that turnbuckle 1140A is free to rotate within opening 1120A.

At least one end of turnbuckle 1140 may still further include an indentation. In an embodiment, each end of turnbuckle 1140 includes an indentation. Indentation 1148 is visible in FIG. 51A; indentations 1148

and 1149 are visible in FIG. 51B. The indentations may be configured to receive the tip of an adjusting tool. The adjusting tool may be a screwdriver. In a preferred embodiment, the adjusting tool is an allen wrench. The adjusting tool may be used to rotate the turnbuckle. Rotation of turnbuckle 1140 in a first direction may cause the cam blocks to move away from each other; rotation of turnbuckle 1140 in a direction opposite the first direction may cause the cam blocks to move toward each other.

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As depicted in FIGs. 50A-50C, cam blocks 1150 and 1160 and sloped tracks 1130, 1132, 1134, and 1136 may be configured such that motion of the cam blocks toward first narrow edge 1108 and second narrow edge 1110 causes the height between the engaging plates to increase. The cam blocks and sloped tracks, however, may be configured such that motion of the cam blocks toward the first and second narrow edges causes the height between the engaging plates to decrease.

FIG. 52A is a top view of fusion devices 1100L and 1100R inserted between two vertebrae (shown in phantom). Anterior edge 1190, posterior edge 1192, first side edge 1194, and second side edge 1196 of the vertebrae are as indicated. As pictured, the first narrow edge of alignment device 1100L is oriented toward anterior edge 1190 of the vertebrae, and the second narrow edge of alignment device 1100R is oriented toward anterior edge 1190. Alternatively, the first narrow edge of each alignment device may be oriented toward anterior edge 1190; the second narrow edge of each alignment device may be oriented toward anterior edge 1190; or the first narrow edge of alignment device 1100R and the second narrow edge of alignment device 1100L may be oriented toward anterior edge 1190.

To install the fusion devices, a discectomy is preferably performed from an anterior approach. All cartilage and soft tissue are preferably removed from the vertebral endplate as would normally be done for placement for a femoral strut graft. Such a procedure is well within the knowledge of a skilled practitioner of the art. The engaging plates may be deployed in the disc space between adjacent vertebrae. FIG. 52B is a front (anterior) view of alignment devices 1100L and 1100R installed in the intervertebral disc space.

Turnbuckles 1140L and 1140R may be rotated to achieve the desired heights 1180L and 1180R between outer surfaces of the engaging plates. The proper heights may be determined beforehand using x-ray techniques in which the side portions of the intervertebral disc space are examined. Bone graft material 1188 may be packed between alignment devices 1100L and 1100R to facilitate fusion of the vertebrae.

Further modifications and alternative embodiments of various aspects of the invention will be apparent to those skilled in the art in view of this description. Accordingly, this description is to be construed as illustrative only and is for the purpose of teaching those skilled in the art the general manner of carrying out the invention. It is to be understood that the forms of the invention shown and described herein are to be taken as the presently preferred embodiments. Elements and materials may be substituted for those illustrated and described herein, parts and processes may be reversed, and certain features of the invention may be utilized independently, all as would be apparent to one skilled in the art after having the benefit of this description of the invention. Changes may be made in the elements described herein without departing from the spirit and scope of the invention as described in the following claims.

## WHAT IS CLAIMED IS:

1. A spinal implant for facilitating a fusion between neighboring vertebrae of a human spine, comprising:

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an anterior end opposite a posterior end;

a pair of engaging plates adapted to fit between and engage the vertebrae to maintain a disk space between the vertebrae during use; and

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an alignment device positionable between the engaging plates, the alignment device being adapted to separate the engaging plates during use such that a height exists therebetween, the height being adjustable such that the height proximate the anterior end differs from the height proximate the posterior end to substantially maintain a natural curvature of the human spine during use.

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2. The spinal implant of claim 1 wherein the alignment device is operable to adjust the height between the engaging plates proximate the anterior end and independently adjust the height between the engaging plates proximate the posterior end.

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subsidence of the vertebrae.

The spinal implant of claim 1 wherein the engaging plates are substantially planar so as to inhibit

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4. The spinal implant of claim 1 wherein the engaging plates comprise a plurality of openings to allow bone growth to occur through the engaging plates.

The spinal implant of claim 1 wherein the engaging plates comprise a plurality of openings, and

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6. The spinal implant of claim 1 wherein the alignment device comprises a screw, and wherein rotation

further comprising bone graft packed between the engaging plates.

of the screw alters the height between the engaging plates during use.

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7. The spinal implant of claim 1 wherein the alignment device comprises a strut extending between the engaging plates.

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8. The spinal implant of claim 1 wherein the alignment device comprises a strut extending between the engaging plates, the strut comprising a hinge to allow an upper member of the strut to pivot with respect to a lower member of the strut.

The spinal implant of claim 1, further comprising a first side and a second side opposite the first side, and wherein the alignment device comprises a first strut and a second strut, the first strut extending between the engaging plates along a location proximate the first side, the second strut extending between the engaging plates along a location proximate the second side, and wherein the first strut and the second strut have different heights such that the height proximate the first side is different than the height proximate the second side.

10. The spinal implant of claim 1, further comprising protrusions extending from at least one of the engaging plates for enhancing an engagement between the vertebra and the engaging plate.

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- 11. The spinal implant of claim 1, further comprising protrusions extending from at least one of the engaging plates for enhancing an engagement between the vertebra and the engaging plate, the protrusions being adapted to extend into the vertebra.
- 15 12. The spinal implant of claim 1, further comprising a first side and a second side located opposite the first side, and wherein the alignment device comprises a first strut and a second strut, the first strut comprising a hinge and extending between the engaging plates along a location proximate the first side, the second strut comprising a hinge and extending between the engaging plates along a location proximate the second side, and wherein the first strut and the second strut have different heights such that the height proximate the first side is different than the height proximate the second side.
  - 13. The spinal implant of claim 1, further comprising a retaining plate proximate the posterior end for maintaining bone graft between the engaging plates.
- 25 14. The spinal implant of claim 1, further comprising a removable end cap proximate the anterior end for maintaining bone graft between the engaging plates.
  - 15. The spinal implant of claim 1 wherein at least one of the engaging plates comprises a face and openings, the openings extending through the face to allow bone growth to occur through the engaging plate, and wherein the openings have a total area that is between about 60 percent and about 80 percent of a total surface area of the face.
  - 16. The spinal implant of claim 1 wherein at least one of the engaging plates comprises a face and openings, the openings extending through the face to allow bone growth to occur through the engaging plate, and wherein the openings have a total area that is greater than about 50 percent of a total surface area of the face.

17. The spinal implant of claim 1, further comprising a strut extending between the engaging plates to define the height between the engaging plates, the strut being deflectable to cause stress to be applied to bone in the vicinity of the implant.

- The spinal implant of claim 1, further comprising a strut extending between the engaging plates, and wherein each of the engaging plates comprises a slot for receiving an end of the strut.
  - 19. The spinal implant of claim 1, further comprising a strut extending between the engaging plates, and wherein each of the engaging plates comprises a slot having a substantially dovetail-shaped cross-section for receiving an end of the strut.
  - 20. The spinal implant of claim 1, further comprising a strut extending between the engaging plates, and wherein each of the engaging plates comprises a slot for receiving an end of the strut, the slot having a width that narrows in a direction from the anterior end to the posterior end, the width of the slot proximate the posterior end being less than a width of the end of the strut such that a locking taper engagement is formable between the slot and the end of the strut.
  - 21. The spinal implant of claim 1 wherein the engaging plates comprise titanium.
- 20. The spinal implant of claim 1, further comprising a strut having a length and extending between the engaging plates, the strut comprising a height that varies along its length such that the height between the engaging plates differs between the anterior end and the posterior end.
- 23. A spinal implant for facilitating a fusion between neighboring vertebrae of a human spine,comprising:
  - a first side opposite a second side;

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an anterior end opposite a posterior end;

a pair of engaging plates adapted to fit between and engage the vertebrae to maintain a disk space between the vertebrae during use;

a first strut adapted to extend between the engaging plates to separate the engaging plates at a location proximate the first side during use;

a second strut adapted to extend between the engaging plates to separate the engaging plates at a location proximate the second side during use;

and wherein the struts are positionable between the engaging plates such that a height between the engaging plates differs between the anterior end and the posterior end whereby a substantially natural curvature of the human spine is maintained during use.

- The spinal implant of claim 23 wherein the first strut and the second strut each comprise a height, the height of the first strut being different than the height of the second strut.
  - 25. The spinal implant of claim 23 wherein the first strut and the second strut each comprise a hinge to allow an upper member of each strut to pivot with respect to a lower member of each strut.
  - 26. The spinal implant of claim 23 wherein the first strut and the second strut have a height, the height of the first strut being different than the height of the second strut, and wherein the first strut and the second strut each comprise a hinge allowing the struts to pivot.
- 15 27. The spinal implant of claim 23 wherein the engaging plates are substantially planar so as to inhibit subsidence of the vertebrae.

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- 28. The spinal implant of claim 23 wherein the engaging plates comprise a plurality of openings to allow bone growth to occur through the engaging plates.
- 29. The spinal implant of claim 23 wherein the engaging plates comprise a plurality of openings, and further comprising bone graft packed between the engaging plates.
- 30. The spinal implant of claim 23, further comprising protrusions extending from at least one of the engaging plates for enhancing an engagement between the vertebra and the engaging plate.
  - 31. The spinal implant of claim 23, further comprising protrusions extending from at least one of the engaging plates for enhancing an engagement between the vertebra and the engaging plate, the protrusions being adapted to extend into the vertebra.
  - 32. The spinal implant of claim 23 further comprising a retaining plate proximate the posterior end for maintaining bone graft between the engaging plates.
  - 33. The spinal implant of claim 23 further comprising a removable end cap proximate the anterior end for maintaining bone graft between the engaging plates.
    - 34. The spinal implant of claim 23 wherein at least one of the engaging plates comprises a face and openings, the openings extending through the face to allow bone growth to occur through the engaging plate,

and wherein the openings have a total area that is between about 60 percent and about 80 percent of a total surface area of the face.

- 35. The spinal implant of claim 23 wherein at least one of the engaging plates comprises a face and openings, the openings extending through the face to allow bone growth to occur through the engaging plate, and wherein the openings have a total area that is greater than about 50 percent of a total surface area of the face.
- 36. The spinal implant of claim 23 wherein the first and second struts are substantially deflectable to cause stress to be applied to bone in the vicinity of the implant.
  - 37. The spinal implant of claim 23 wherein each of the engaging plates comprises a pair of slots for receiving ends of the first and second struts.
- 15 38. The spinal implant of claim 23 wherein each of the engaging plates comprises a slot having a substantially dovetail-shaped cross-section for receiving an end of one of the struts.
  - 39. The spinal implant of claim 23 wherein each of the engaging plates comprises a pair of slots for receiving ends of the first and second struts, the slots each having a width that narrows in a direction from the anterior end to the posterior end, the width of each of the slots proximate the posterior end being less than a width of the ends of the struts such that a locking taper engagement is formable between the slots and the ends of the struts.
  - 40. The spinal implant of claim 23 wherein the engaging plates comprise titanium.
  - The spinal implant of claim 23 wherein the first and second struts comprise a height that varies along a length of the struts such that the height between the engaging plates differs between the anterior end and the posterior end.
- 30 42. A spinal implant for facilitating a fusion between neighboring vertebrae of a human spine, comprising:
  - a first side opposite a second side;

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a pair of engaging plates adapted to fit between and engage the vertebrae to maintain a disk space between the vertebrae during use, the engaging plates each comprising a slot;

a first pin and a second pin adapted to be disposed within the slots during use, the pins being substantially elongated and positionable to extend in a direction from the first side to the second side during use; and

- a connector for engaging the pins, the connector being rotatable to move one of the pins relative to the other, thereby altering a height between the engaging plates to maintain a substantially natural curvature of the spine during use.
- 43. The spinal implant of claim 42 wherein the engaging plates are substantially planar so as to inhibit subsidence of the vertebrae.
  - The spinal implant of claim 42 wherein the engaging plates comprise a plurality of openings to allow bone growth to occur through the engaging plates.
- 15 45. The spinal implant of claim 42 wherein the engaging plates comprise a plurality of openings, and further comprising bone graft packed between the engaging plates.

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- 46. The spinal implant of claim 42, further comprising protrusions extending from at least one of the engaging plates for enhancing an engagement between the vertebra and the engaging plate.
- 47. The spinal implant of claim 42, further comprising protrusions extending from at least one of the engaging plates for enhancing an engagement between the vertebra and the engaging plate, the protrusions being adapted to extend into the vertebra.
- 25 48. The spinal implant of claim 42, further comprising a retaining plate proximate the posterior end for maintaining bone graft between the engaging plates.
  - 49. The spinal implant of claim 42, further comprising a removable end cap proximate the anterior end for maintaining bone graft between the engaging plates.
  - 50. The spinal implant of claim 42 wherein at least one of the engaging plates comprises a face and openings, the openings extending through the face to allow bone growth to occur through the engaging plate, and wherein the openings have a total area that is between about 60 percent and about 80 percent of a total surface area of the face.
  - 51. The spinal implant of claim 42 wherein at least one of the engaging plates comprises a face and openings, the openings extending through the face to allow bone growth to occur through the engaging plate,

and wherein the openings have a total area that is greater than about 50 percent of a total surface area of the face.

- 52. The spinal implant of claim 42 wherein the connector is a screw having a threaded portion.
- 53. The spinal implant of claim 42 wherein the engaging plates comprise titanium.

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- 54. The spinal implant of claim 42 wherein the engaging plates each further comprise a rib and a face, the rib extending in a substantially perpendicular direction from the face, the rib comprising the slot for receiving one of the pins.
- 55. The spinal implant of claim 42 wherein the engaging plates each further comprise a rib comprising the slot into which the pins extend.
- 15 56. The spinal implant of claim 42 wherein the connector is a screw adapted to move axially between the engaging plates, and wherein the screw further comprises a retaining ring for contacting a portion of at least one of the engaging plates to limit movement of the screw.
  - 57. The spinal implant of claim 42 wherein the first pin comprises a threaded opening, and wherein the connector is a screw comprising a threaded portion and an unthreaded portion, the threaded portion extending through the threaded opening, the second pin being connected to the unthreaded portion.
    - 58. The spinal implant of claim 42, further comprising an anterior end and a posterior end, and wherein the connector is adapted to move axially between the engaging plates in a direction from the anterior end to the posterior end, thereby moving the first pin toward the anterior end and the second pin toward the posterior end to increase the height.
    - 59. The spinal implant of claim 42 wherein one of the slots comprises a first end and wherein the other slot comprises a second end, the first end and the second end extending in diverging directions, and wherein movement of one of the pins draws the first end and the second end together.
    - 60. The spinal implant of claim 42 wherein the pins comprise an end and a receiving section, the end being disposed within one of the slots, the receiving section containing an opening for receiving the connector, the receiving section having a greater width than the end of the pin.
    - 61. The spinal implant of claim 42 wherein the engaging plates each further comprise a rib and a face, the rib extending from the face in substantially perpendicular direction, and wherein the slot extends along a length of the rib.

62. The spinal implant of claim 42, further comprising an anterior end and a posterior end, and wherein movement of the pins alters the height proximate the anterior end at a faster rate than the height proximate the posterior end.

5 63. A spinal implant for facilitating a fusion between neighboring vertebrae of a human spine, comprising:

an anterior end opposite a posterior end;

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a pair of engaging plates adapted to fit between and engage the vertebrae to maintain a disk space between the vertebrae during use;

a strut adapted to be inserted between the engaging plates to separate the engaging plates, the strut extending in a direction from the anterior end to the posterior end during use; and

a load-sharing member axially positionable within the strut, the load-sharing member being substantially deflectable to allow movement of one of the engaging plates during use.

- 64. The spinal implant of claim 63, further comprising a bore extending axially through the strut, the load-sharing member being disposed within the bore, the bore having a greater width than the load-sharing member to provide space for deflection of the load-sharing member.
  - The spinal implant of claim 63, further comprising a connector for engaging the load-sharing member, the connector being adapted to impart force to the load-sharing member to deflect the load-sharing member.
  - 66. The spinal implant of claim 63, further comprising a screw engaging the load-sharing member, the screw being adapted to impart force to the load-sharing member to deflect the load-sharing member.
- 30 67. The spinal implant of claim 63, further comprising a screw for engaging the load-sharing member, and wherein the strut further comprises a threaded opening, the screw being disposed within the threaded opening.
- 68. The spinal implant of claim 63 wherein the strut further comprises an upper member and a lower member, the upper member being pivotable with respect to the lower member about the load-sharing member.
  - 69. The spinal implant of claim 63 wherein the load-sharing member is a substantially cylindrical pin, and wherein the load-sharing member further comprises an indention having a substantially planar surface.

70. The spinal implant of claim 63 wherein the strut comprises an upper member and a lower member, and further comprising a predetermined spacing between the upper and lower members, and wherein application of a compressive force onto the engaging plates decreases the predetermined spacing.

- The spinal implant of claim 63 wherein the strut comprises an upper member and a lower member, and further comprising a predetermined spacing between the upper and lower members, and further comprising a connector engaging the load-sharing member, and wherein the predetermined spacing is adjustable by altering the position of the connector.
- 10 72. The spinal implant of claim 63, further comprising a connector engaging the load-sharing member at a fulcrum point, and further comprising a support location where the strut contacts the load-sharing member, the support location and the fulcrum point being separated by a predetermined distance such that an effective modulus of elasticity of the implant is substantially equal to a modulus of elasticity of bone.
- The spinal implant of claim 63 wherein deflection of the load-sharing member is adapted to impart stress to bone graft proximate the engaging plates to promote a spinal fusion.
  - 74. A spinal implant for facilitating a fusion between neighboring vertebrae of a human spine, comprising:

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a pair of engaging plates adapted to fit between and engage the vertebrae to maintain a disk space between the vertebrae;

a load-sharing member positionable between the engaging plates to separate the engaging plates, the load-sharing member being substantially deflectable to allow the engaging plates to move a predetermined distance toward one another upon application of a compressive force onto the engaging plates during use; and

an effective modulus of elasticity in the vicinity of a modulus of elasticity of bone.

30 75. A method for facilitating a fusion between neighboring vertebrae of a human spine, comprising:

inserting a spinal implant between the vertebrae, the spinal implant comprising an anterior end, a posterior end opposite the anterior end, and a pair of engaging plates for engaging the vertebrae; and

adjusting an alignment device disposed between the engaging plates to adjust a height between the engaging plates such that the height proximate the anterior end differs from the height proximate the posterior end to maintain a substantially natural curvature of the spine.

76. The method of claim 75 wherein the height between the engaging plates proximate the anterior end and the height between the engaging plates proximate the posterior end are adjusted independently of one another.

The method of claim 75 wherein the engaging plates are substantially planar so as to inhibit subsidence of the vertebrae.

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- 78. The method of claim 75 wherein the engaging plates comprise a plurality of openings, and further comprising placing bone graft between the engaging plates.
- 79. The method of claim 75 wherein the alignment device comprises a screw, and further comprising rotating the screw to adjust the height between the engaging plates.
- 80. The method of claim 75 wherein the alignment device comprises a strut, and wherein adjusting the alignment device comprises positioning the strut between the engaging plates.
  - The method of claim 75 wherein the alignment device comprises a strut extending between the engaging plates, the strut comprising an upper member, a lower member, and a hinge, and further comprising pivoting the upper member with respect to the lower member about the hinge.
  - 82. The method of claim 75 wherein the spinal implant further comprises a first side and a second side opposite the first side, and wherein the alignment device comprises a first strut and a second strut, the first strut extending between the engaging plates along a location proximate the first side, the second strut extending between the engaging plates along a location proximate the second side, and wherein the first strut and the second strut have different heights such that the height proximate the first side is different than the height proximate the second side.
  - 83. The method of claim 75 wherein at least one of the engaging plates comprises protrusions for enhancing an engagement between the vertebra and the engaging plate.
  - 84. The method of claim 75 wherein at least one of the engaging plates comprises protrusions for enhancing an engagement between the vertebra and the engaging plate, and wherein the protrusions extend into the vertebra.
- 85. The method of claim 75 wherein the spinal implant further comprises a first side and a second side located opposite the second side, and wherein the alignment device comprises a first strut and a second strut, the first strut comprising a hinge and extending between the engaging plates along a location proximate the first side, the second strut comprising a hinge and extending between the engaging plates along a location

proximate the second side, and further comprising bending each of the first and second struts about the hinges, and wherein the first strut and the second strut have different heights such that the height proximate the first side is different than the height proximate the second side.

- 5 86. The method of claim 75 wherein the spinal implant further comprises a retaining plate proximate the posterior end for maintaining bone graft between the engaging plates.
  - 87. The method of claim 75, further comprising placing a removable endcap proximate the anterior end to maintaining bone graft between the engaging plates.

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- 88. The method of claim 75 wherein at least one of the engaging plates comprises a face and openings, the openings extending through the face to allow bone growth to occur through the engaging plate, and wherein the openings have a total area that is between about 60 percent and about 80 percent of a total surface area of the face.
- 89. The method of claim 75 wherein at least one of the engaging plates comprises a face and openings, the openings extending through the face to allow bone growth to occur through the engaging plate, and wherein the openings have a total area that is greater than about 50 percent of a total surface area of the face.
- 20 90. The method of claim 75 wherein the alignment device comprises a strut extending between the engaging plates to define the height between the engaging plates, and further comprising deflecting the strut to cause stress to be applied to bone in the vicinity of the implant to promote bone growth.
  - 91. The method of claim 75 wherein the alignment device comprises a strut, and wherein adjusting the alignment device comprises inserting an end of the strut into a slot located on one of the engaging plates.
    - 92. The method of claim 75 wherein the alignment device comprises a strut having a substantially dovetail-shaped end, and wherein adjusting the alignment device comprises inserting the end into a slot located on one of the engaging plates, the slot having a substantially dovetail-shaped cross-section.
  - 93. The method of claim 75 wherein the alignment device comprises a strut extending between the engaging plates, and wherein each of the engaging plates comprises a slot for receiving an end of the strut, the slot having a width that narrows in a direction from the anterior end to the posterior end, the width of the slot proximate the posterior end being less than a width of the end of the strut, and further comprising sliding the end of the strut into the slot to form a locking taper engagement between the slot and the end of the strut.

The method of claim 75 wherein the alignment device comprises a strut having a length and extending between the engaging plates, the strut comprising a height that varies along its length such that the height between the engaging plates differs between the anterior end and the posterior end.

95. A method for facilitating a fusion between neighboring vertebrae of a human spine, comprising:

inserting a spinal implant between the vertebrae, the spinal implant comprising a first side, a second side opposite the first side, an anterior end, a posterior end opposite the anterior end, and a pair of engaging plates for engaging the vertebrae;

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separating the engaging plates such that a predetermined height exists between the engaging plates, and wherein the predetermined height varies between the anterior end and the posterior end to maintain a substantially natural curvature of the human spine; and

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inserting a first strut and a second strut between the engaging plates to maintain the predetermined height between the engaging plates.

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The method of claim 95 wherein the first strut extends between the anterior end and the posterior end along a location proximate the first side, and wherein the second strut extends between the anterior end and the posterior end along a location proximate the second side.

97. The method of claim 95 wherein the first and second struts define the predetermined height, and wherein each of the struts comprises a length and a height, the height of each of the struts varying along the length such that the predetermined height increases in a direction from the posterior end to the anterior end.

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98. The method of claim 95 wherein the first strut and the second strut each comprise a height, the height of the first strut being different than the height of the second strut.

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99. The method of claim 95 wherein the first strut and the second strut each comprise a hinge, an upper member, and a lower member, and further comprising pivoting the upper member with respect to the lower member of each of the struts.

100. The method of claim 95 wherein the engaging plates are substantially planar so as to inhibit subsidence of the vertebrae.

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101. The method of claim 95 wherein the engaging plates comprise a plurality of openings to allow bone growth to occur through the engaging plates.

102. The method of claim 95 wherein the engaging plates comprise a plurality of openings, and further comprising placing bone graft between the engaging plates.

103. The method of claim 95 wherein at least one of the engaging plates comprises protrusions for enhancing an engagement between the vertebra and the engaging plate.

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- 104. The method of claim 95 wherein at least one of the engaging plates comprises protrusions for enhancing an engagement between the vertebra and the engaging plate, the protrusions being adapted to extend into the vertebra.
- 105. The method of claim 95 wherein the spinal implant further comprises a retaining plate proximate the posterior end for maintaining bone graft between the engaging plates.
- 106. The method of claim 95, further comprising placing a removable end cap proximate the anterior end to maintain bone graft between the engaging plates.
  - 107. The method of claim 95 wherein at least one of the engaging plates comprises a face and openings, the openings extending through the face to allow bone growth to occur through the engaging plate, and wherein the openings have a total area that is between about 60 percent and about 80 percent of a total surface area of the face.
  - 108. The method of claim 95 wherein at least one of the engaging plates comprises a face and openings, the openings extending through the face to allow bone growth to occur through the engaging plate, and wherein the openings have a total area that is greater than about 50 percent of a total surface area of the face.
  - 109. The method of claim 95 wherein each of the engaging plates comprises a pair of slots, and wherein the first strut and the second strut each comprise a pair of ends, and wherein inserting the first and second struts between the engaging plates comprises inserting the ends into the slots.
- 30 110. The method of claim 95 wherein each of the engaging plates comprises a pair of slots, each of the slots comprising a substantially dovetail-shaped cross section, and wherein the first strut and the second strut each comprise a pair of ends, the ends having a substantially dovetail shape, and wherein inserting the first and second struts between the engaging plates comprises inserting the ends into the slots.
- 35 111. The method of claim 95 wherein each of the engaging plates comprises a pair of slots for receiving ends of the first and second struts, the slots each having a width that narrows in a direction from the anterior end to the posterior end, the width of each of the slots proximate the posterior end being less than a width of

the ends of the struts, and further comprising sliding the ends of the struts into slots such that a locking taper engagement is formed between the slots and the ends of the struts.

112. The method of claim 95 wherein the first and second struts comprise a height that varies along a length of the struts such that the height between the engaging plates differs between the anterior end and the posterior end.

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113. A method for facilitating a fusion between neighboring vertebrae of a human spine, comprising:

side opposite the first side, a pair of engaging plates for engaging the vertebrae, a first pin, a second pin, and a connector engaging the first and second pins, the engaging plates each comprising a slot, the first and second pins being disposed within the slots and extending in a direction from the first side to the second side;

rotating the connector to move one of the pins relative to the other, thereby altering a height between the engaging plates to maintain a substantially natural curvature of the spine.

- 114. The method of claim 113 wherein the engaging plates are substantially planar so as to inhibit subsidence of the vertebrae.
- 115. The method of claim 113 wherein the engaging plates comprise a plurality of openings to allow bone growth to occur through the engaging plates.
- The method of claim 113 wherein the engaging plates comprise a plurality of openings to allow bone growth to occur through the engaging plates, and further comprising placing bone graft between the engaging plates.
  - 117. The method of claim 113 wherein at least one of the engaging plates further comprises protrusions for enhancing an engagement between the vertebra and the engaging plate.
  - 118. The method of claim 113 wherein at least one of the engaging plates further comprises protrusions for enhancing an engagement between the vertebra and the engaging plate, and further comprising contacting the vertebra with the engaging plate so that the protrusions extend into the vertebra.
- 35 119. The method of claim 113 wherein the spinal implant further comprises a retaining plate proximate the posterior end for maintaining bone graft between the engaging plates.

120. The method of claim 113, further comprising placing a removable end cap proximate the anterior end to maintain bone graft between the engaging plates.

- 121. The method of claim 113 wherein at least one of the engaging plates comprises a face and openings, the openings extending through the face to allow bone growth to occur through the engaging plate, and wherein the openings have a total area that is between about 60 percent and about 80 percent of a total surface area of the face.
- 122. The method of claim 113 wherein at least one of the engaging plates comprises a face and openings, the openings extending through the face to allow bone growth to occur through the engaging plate, and wherein the openings have a total area that is greater than about 50 percent of a total surface area of the face.
  - 123. The method of claim 113 wherein the connector is a screw having a threaded portion.

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- 15 124. The method of claim 113 wherein the engaging plates each further comprise a rib and a face, the rib extending in a substantially perpendicular direction from the face, the rib comprising the slot for receiving the pins.
- 125. The method of claim 113 wherein the engaging plates each further comprise a rib comprising the slot 20 into which the pins extend.
  - 126. The method of claim 113 wherein rotating the connector moves the connector axially between the engaging plates, and wherein the connector further comprises a retaining ring for contacting a portion of at least one of the engaging plates to limit movement of the connector.
  - 127. The method of claim 113 wherein the first pin comprises a threaded opening, and wherein the connector is a screw comprising a threaded portion and an unthreaded portion, the threaded portion extending through the threaded opening, the second pin being connected to the unthreaded portion.
- 30 128. The method of claim 113, further comprising an anterior end and a posterior end, and wherein rotating the connector moves the connector axially between the engaging plates in a direction from the anterior end to the posterior end, thereby moving the first pin toward the anterior end and the second pin toward the posterior end to increase the height.
- The method of claim 113 wherein one of the slots comprises a first end, and wherein the other slot comprises a second end, the first end and the second end extending in diverging directions, and wherein rotation of the connector causes movement of one of the pins to draw the first end and the second end together, thereby altering the height between the engaging plates.

130. The method of claim 113 wherein the pins comprise an end and a receiving section, the end being disposed within one of the slots, the receiving section containing an opening for receiving the connector, the receiving section having a greater width than the end of the pin.

- The method of claim 113 wherein the engaging plates each further comprise a rib and a face, the rib extending from the face in substantially perpendicular direction, and wherein the slot extends along a length of the rib.
- 132. The method of claim 113, further comprising an anterior end and a posterior end, and wherein rotation of the connector alters the height proximate the anterior end at a faster rate than the height proximate the posterior end.
  - 133. A method for facilitating a fusion between neighboring vertebrae of a human spine, comprising:

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inserting a spinal implant between the vertebrae, the spinal implant comprising a first side, a second side opposite the first side, an anterior end, a posterior end opposite the anterior end, and a pair of engaging plates for engaging the vertebrae;

separating the engaging plates such that a predetermined height exists between the engaging plates, and wherein the predetermined height varies between the anterior end and the posterior end to maintain a substantially natural curvature of the human spine; and

inserting a strut between the engaging plates to maintain the predetermined height between the engaging plates, the strut comprising a substantially deflectable load-sharing member:

applying a force to the load sharing member, thereby imparting stress to bone in the vicinity of the spinal implant to promote the spinal fusion.

- 134. The method of claim 133 wherein the load-sharing member is disposed in a bore axially disposed in the strut, the bore having a greater width than the load-sharing member to provide space for deflection of the load-sharing member.
- 135. The method of claim 133 wherein the strut further comprises a connector for engaging the load-sharing member, the connector adapted to impart force to the load-sharing member to deflect the load-sharing member.

136. The method of claim 133 wherein the strut further comprises a screw engaging the load-sharing member, the screw being adapted to impart force to the load-sharing member to deflect the load-sharing member.

- 5 137. The method of claim 133, further comprising a screw for engaging the load-sharing member, and wherein the strut further comprises a threaded opening, the screw being disposed within the threaded opening.
  - 138. The method of claim 133 wherein the strut further comprises an upper member and a lower member, and further comprising pivoting the upper member with respect to the lower member.
  - 139. The method of claim 133 wherein the load-sharing member is a substantially cylindrical pin, and wherein the load-sharing member further comprises an indention having a substantially planar surface, and wherein the force is applied to the substantially planar surface.
- 15 140. The method of claim 133 wherein the strut comprises an upper member and a lower member, and wherein a predetermined spacing exists between the upper and lower members, and further comprising applying a compressive force onto the engaging plates, thereby decreasing the predetermined spacing.

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- 141. The method of claim 133 wherein the strut comprises an upper member and a lower member, and
  wherein a predetermined spacing exists between the upper and lower members, and wherein the strut further
  comprises a connector engaging the load-sharing member, and further comprising adjusting the predetermined
  spacing by changing the position of the connector.
- 142. The method of claim 133 wherein the strut further comprises a connector engaging the load-sharing member at a fulcrum point, the strut further comprising a support location for contacting the load-sharing member, the support location and the fulcrum point being separated by a predetermined distance such that an effective modulus of elasticity of the implant is substantially equal to a modulus of elasticity of bone.
- 143. The method of claim 133 wherein deflection of the load-sharing member imparts stress to bone graft proximate the engaging plates to promote the fusion.
  - 144. The method of claim 133 wherein the force comprises compressive force from the weight of the spine.
  - 145. A spinal implant for facilitating a fusion between neighboring vertebrae of a spine, comprising:

    an anterior edge located opposite a posterior edge;

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a first side edge located opposite a second side edge;

a pair of engaging plates configured to fit between and engage the vertebrae to maintain a disk space between the vertebrae during use, the engaging plates each comprising a length substantially between the anterior and posterior edges, the engaging plates each comprising a width substantially between the first side edge and the second side edge;

a first alignment device positionable between the engaging plates and capable of separating the engaging plates at a first location proximate the anterior edge during use; and

a second alignment device positionable between the engaging plates and capable of separating the engaging plates at a second location proximate the first side edge during use; and

wherein the first alignment device is adjustable during use to substantially maintain a first height between the engaging plates along a direction substantially from the anterior edge to the posterior edge, thereby substantially maintaining a natural curvature of the spine during use; and

wherein the second alignment device is adjustable during use to substantially maintain a second height between the engaging plates along a direction substantially from the first side edge to the second side edge, thereby substantially maintaining a natural position of the spine during use.

- 146. The spinal implant of claim 145 wherein the first height proximate the anterior edge is in the range from less than about the first height proximate the posterior edge to greater than about the first height proximate the posterior edge.
- 147. The spinal implant of claim 145 wherein the second height proximate the first side edge is in the range from less than about the second height proximate the second side edge to greater than about the second height proximate the second side edge.
- The spinal implant of claim 145 wherein the first height proximate the anterior edge is in the range from less than about the first height proximate the posterior edge to greater than about the first height proximate the posterior edge and wherein the second height proximate the first side edge is in the range from less than about the second height proximate the second side edge to greater than about the second height proximate the second side edge.
  - 149. The spinal implant of claim 145 wherein each of the alignment devices comprises:
    - a screw, wherein the screw comprises threading; and

a cam block, wherein the cam block comprises a sloped outer surface, and wherein the cam block includes an opening having internal threading complementary to the threading of the screw.

150. The spinal implant of claim 145 wherein an inner surface of each of the engaging plates includes arcuate grooves configured to correspond to a shape of the alignment devices.

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- 151. The spinal implant of claim 145, further comprising a bracket assembly configured to separate the engaging plates during use, and wherein the bracket assembly supports the first and second alignment devices.
- 10 152. The spinal implant of claim 145 wherein at least one of the alignment devices comprises cam blocks, and wherein an inner surface of each of the engaging plates includes sloped tracks formed therein, the sloped tracks being configured such that motion of the cam blocks during use causes at least one of the first height and the second height to vary.
- 153. The spinal implant of claim 145 wherein at least one of the alignment devices comprises cam blocks, and wherein an inner surface of each of the engaging plates includes sloped tracks formed therein, the sloped tracks being configured such that motion of the cam blocks during use causes at least one of the first height and the second height to vary, and wherein each of the cam blocks comprises an upper surface and a lower surface, the upper surface and the lower surface being sloped to conform to the sloped tracks in the inner surfaces of the engaging plates.
  - 154. The spinal implant of claim 153 wherein the surfaces of the cam blocks and the sloped tracks in the inner surfaces of the engaging plates are configured such that movement of the cam blocks toward the exterior of the spinal implant increases at least one of the first height and the second height during use and such that movement of the cam blocks away from the exterior of the spinal implant decreases at least one of the first height and the second height during use.
  - 155. The spinal implant of claim 153 wherein the surfaces of the cam blocks and the sloped tracks in the inner surfaces of the engaging plates are configured such that movement of the cam blocks toward the exterior of the spinal implant decreases at least one of the first height and the second height during use and such that movement of the cam blocks away from the exterior of the spinal implant increases at least one of the first height and the second height during use.
  - 156. The spinal implant of claim 145 wherein the spinal implant comprises a biocompatible material selected from the group consisting of ceramic, metal, polymer, and composite material.
  - 157. The spinal implant of claim 145 wherein the engaging plates are substantially planar so as to inhibit subsidence of the vertebrae during use.

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- 158. The spinal implant of claim 145 wherein the engaging plates comprise a plurality of openings to allow bone growth to occur through the engaging plates during use.
- 159. The spinal implant of claim 145, further comprising bone graft material packed between the engaging plates, wherein the engaging plates comprise a plurality of openings to allow bone growth to occur through the engaging plates during use.
  - 160. The spinal implant of claim 145, further comprising protrusions extending from at least one of the engaging plates for enhancing an engagement between the spine and the spinal implant during use.
  - 161. The spinal implant of claim 145, further comprising protrusions extending from at least one of the engaging plates for enhancing an engagement between the spine and the spinal implant during use, the protrusions being adapted to extend into the spine.
- 15 162. The spinal implant of claim 145, further comprising bone graft material and a retaining plate, the bone graft material being packed between the engaging plates, the retaining plate being configured to keep the bone graft material between the engaging plates during use.
- 163. The spinal implant of claim 145 wherein at least one of the engaging plates comprises a face and openings extending through the face to allow bone growth to occur through the engaging plate during use, the openings having a total area that is greater than about 50 percent of a total surface area of the face.
  - 164. The spinal implant of claim 145 wherein at least one of the engaging plates comprises a face and openings extending through the face to allow bone growth to occur through the engaging plate during use, the openings having a total area that is between about 60 percent and about 80 percent of a total surface area of the face.
  - 165. The spinal implant of claim 145 wherein an end of each of the aligning devices includes an indentation and wherein a tip of an adjusting tool may be inserted into the indentation such that movement of the adjusting tool causes the aligning device including the indentation to move.
  - 166. The spinal implant of claim 165 wherein the adjusting tool comprises a tool selected from the group consisting of screwdrivers and allen wrenches.
- 35 167. A spinal implant for facilitating a fusion between neighboring vertebrae of a spine, comprising:

  an anterior edge located opposite a posterior edge;

a pair of engaging plates configured to fit between and engage the vertebrae to maintain a disk space between the vertebrae during use, the engaging plates each comprising a length substantially between the anterior and posterior edges;

a first alignment device positionable between the engaging plates and capable of separating the engaging plates at a first location proximate the anterior edge during use; and

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a second alignment device positionable between the engaging plates and capable of separating the engaging plates at a second location proximate the posterior edge during use; and

wherein the first and second alignment devices are independently operable of one another during use to substantially maintain a height between the engaging plates along a direction substantially from the anterior edge to the posterior edge, thereby substantially maintaining a natural curvature of the spine during use.

- 168. The spinal implant of claim 167 wherein the height proximate the anterior edge is in the range from less than about the height proximate the posterior edge to greater than about the height proximate the posterior edge.
- 169. A spinal implant for facilitating a fusion between neighboring vertebrae of a spine, comprising:
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  a first side edge located opposite a second side edge;

a pair of engaging plates configured to fit between and engage the vertebrae to maintain a disk space between the vertebrae during use, the engaging plates each comprising a width substantially between the first side edge and the second side edge:

a first alignment device positionable between the engaging plates and capable of separating the engaging plates at a first location proximate the first side edge during use; and

a second alignment device positionable between the engaging plates and capable of separating the engaging plates at a second location proximate the second side edge during use; and

wherein the first and second alignment devices are independently operable of one another during use to substantially maintain a height between the engaging plates along a direction substantially from the first side edge to the second side edge, thereby substantially maintaining a natural position of the spine during use.

170. The spinal implant of claim 169 wherein the height proximate the first side edge is in the range from less than about the height proximate the second side edge to greater than about the height proximate the second side edge.

171. A spinal implant for facilitating a fusion between neighboring vertebrae of a spine, comprising:

an anterior edge located opposite a posterior edge;

a first side edge located opposite a second side edge;

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a pair of engaging plates configured to fit between and engage the vertebrae to maintain a disk space between the vertebrae during use, the engaging plates each extending substantially between the edges, the engaging plates each comprising an inner surface and a substantially elongated track formed into the inner surface;

an alignment device positionable between the engaging plates and capable of maintaining a selected height between the engaging plates along a direction from a first location adjacent one of the edges to a second location adjacent the edge opposite the one of the edges during use, the alignment device comprising:

a cam block sized to fit within the tracks; and

a substantially elongated member configured to rotate during use to cause movement of the cam block within the tracks such that the selected height between the engaging plates is altered during use.

- 172. The implant of claim 171 wherein the elongated member comprises a screw having threading disposed thereon, and wherein the cam block comprises an opening having internal threading complementary to the threading of the screw.
- 173. The implant of claim 171 wherein the cam block comprises a sloped outer surface, and wherein the tracks each comprise a sloped surface shaped to receive the sloped outer surface during use.
- 174. The spinal implant of claim 171 wherein the selected height proximate the first location is in the range from less than about the selected height proximate the second location to greater than about the height proximate the second location.
  - 175. A spinal implant for facilitating fusion between neighboring vertebrae of a spine, comprising:
- a pair of engaging plates configured to fit between and engage the vertebrae to maintain a disk space between the vertebrae during use;
  - a cam block configured to be coupled to inner surfaces of the engaging plates during use; and

a substantially elongated member configured to be coupled to the cam block during use, wherein the substantially elongated member is configured such that rotation of the substantially elongated member in a first angular direction moves the cam block such that a height between the engaging plates is substantially increased during use, and wherein the substantially elongated member is configured such that rotation of the substantially elongated member in a second angular direction moves the cam block such that the height between the engaging plates is substantially decreased during use.

- 176. The spinal implant of claim 175 wherein the substantially elongated member comprises an exterior surface having threading disposed thereon.
- 177. The spinal implant of claim 175 wherein the spinal implant comprises a biocompatible material selected from the group consisting of ceramic, metal, polymer, and composite material.
- 178. The spinal implant of claim 175 wherein the engaging plates are substantially planar so as to inhibit subsidence of the vertebrae during use.
- 179. The spinal implant of claim 175, further comprising protrusions extending from at least one of the engaging plates for enhancing an engagement between the spine and the spinal implant during use.
- 20 180. The spinal implant of claim 175, further comprising protrusions extending from at least one of the engaging plates for enhancing an engagement between the spine and the spinal implant during use, the protrusions being adapted to extend into the spine.
  - 181. The spinal implant of claim 175 wherein at least one end of the substantially elongated member includes an indentation and wherein a tip of an adjusting tool may be inserted into the indentation such that movement of the adjusting tool causes the substantially elongated member to move.
    - 182. The spinal implant of claim 181 wherein the adjusting tool comprises a tool selected from the group consisting of screwdrivers and allen wrenches.
    - 183. The spinal implant of claim 175, further comprising another cam block, and wherein the substantially elongated member comprises a turnbuckle comprising (a) a first end having first threading in a first direction disposed thereon and (b) a second end opposite the first end, the second end having second threading in a second direction opposite the first direction disposed thereon.
    - 184. The spinal implant of claim 183 wherein an inner surface of each of the engaging plates includes arcuate grooves configured to correspond to a shape of the turnbuckle.

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185. The spinal implant of claim 183, further comprising a bracket assembly configured to separate the engaging plates during use, and wherein the bracket assembly supports the turnbuckle.

- 186. The spinal implant of claim 175 wherein an inner surface of each of the engaging plates includes sloped tracks formed therein, the sloped tracks being configured such that motion of the cam blocks during use causes the height to vary, and wherein each of the cam blocks comprises an upper surface and a lower surface, the upper surface and the lower surface being sloped to conform to the sloped tracks in the inner surfaces of the engaging plates.
- 10 187. The spinal implant of claim 186 wherein the surfaces of the cam blocks and the sloped tracks in the inner surfaces of the engaging plates are configured such that movement of the cam blocks toward the ends of the turnbuckle increases the height during use and such that movement of the cam block away from the ends of the turnbuckle decreases at the height during use.
- 15 188. The spinal implant of claim 186 wherein the surfaces of the cam blocks and the sloped tracks in the inner surfaces of the engaging plates are configured such that movement of the cam blocks toward the ends of the turnbuckle decreases the height and such that movement of the cam blocks away from the ends of the turnbuckle increases the height during use.
- 20 189. The spinal implant of claim 183 wherein the bracket assembly includes an arcuate opening supporting an end of the turnbuckle and wherein the end of the turnbuckle includes an indentation and wherein a tip of an adjusting tool may be inserted into the indentation such that movement of the adjusting tool causes the turnbuckle to move.
- 25 190. The spinal implant of claim 183 wherein the bracket assembly includes a pair of arcuate opening supporting the ends of the turnbuckle and wherein each of the ends of the turnbuckle includes an indentation and wherein a tip of an adjusting tool may be inserted into either of the indentations such that movement of the adjusting tool causes the turnbuckle to move.
- The spinal implant of claim 175 wherein the substantially elongated member is oriented substantially parallel to and substantially adjacent an edge of the spinal implant.
  - 192. A spinal implant for facilitating a fusion between neighboring vertebrae of a spine, comprising:
- an anterior edge located opposite a posterior edge;

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a first side edge located opposite a second side edge;

a pair of engaging plates adapted to fit between and engage the vertebrae to maintain a disk space between the vertebrae during use, each of the engaging plates comprising an inner surface;

a first pair of cam blocks configured to be coupled to inner surfaces of the engaging plates during use;

a second pair of cam blocks configured to be coupled to the inner surfaces of the engaging plates during use;

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a first substantially elongated member configured to be coupled to the first pair of cam blocks during use, wherein the first substantially elongated member is configured such that rotation of the first substantially elongated member in a first angular direction moves the first pair of cam blocks such that a first height between the engaging plates is substantially increased during use, and wherein the first substantially elongated member is configured to rotate such that rotation of the first substantially elongated member in an angular direction opposite the first angular direction moves the first pair of cam blocks such that the first height between the engaging plates is substantially decreased during use; and

a second substantially elongated member configured to be coupled to the second pair of cam blocks during use, wherein the second substantially elongated member is configured such that rotation of the second substantially elongated member in a second angular direction moves the second pair of cam blocks such that a second height between the engaging plates is substantially increased during use, and wherein the second substantially elongated member is configured to rotate such that rotation of the second substantially elongated member in an angular direction opposite the second angular direction moves the second pair of cam blocks such that the second height between the engaging plates is substantially decreased during use; and

wherein the first height may be altered such that the second height remains substantially unaltered during use, and wherein the second height may be altered such that the first height remains substantially unaltered during use.

- 193. The spinal implant of claim 192 wherein the first height varies between a first location proximate one of the edges and a second location proximate the edge opposite the one of the edges such that the first height proximate the first location is in the range from less than about the first height proximate the second location to greater than about the first height proximate the second location.
- 35 194. The spinal implant of claim 192 wherein the second height varies between a first location proximate one of the edges and a second location proximate the edge opposite the one of the edges such that the second height proximate the first location is in the range from less than about the second height proximate the second location to greater than about the second height proximate the second location.

195. The spinal implant of claim 192 wherein the first height varies between a first location proximate one of the edges and a second location proximate the edge opposite the one of the edges such that the first height proximate the first location is in the range from less than about the first height proximate the second location to greater than about the first height proximate the second location and wherein the second height varies between a third location proximate another of the edges and a fourth location proximate the edge opposite the another of the edges such that the second height proximate the third location is in the range from less than about the second height proximate the fourth location to greater than about the second height proximate the fourth location.

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196. The spinal implant of claim 192 wherein the first substantially elongated member is oriented substantially parallel to and substantially adjacent one of the edges of the spinal implant, and wherein the second substantially elongated member is oriented substantially parallel to and substantially adjacent an edge of the spinal implant opposite the one of the edges.

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197. The spinal implant of claim 192, further comprising a bracket assembly separating the engaging plates, wherein the bracket assembly supports the first substantially elongated member and the second substantially elongated member.

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198. The spinal implant of claim 197 wherein the bracket assembly comprises ends including arcuate grooves configured to conform to a curvature of the substantially elongated members.

grooves configured to conform to a curvature of the substantially elongated members.

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200. The spinal implant of claim 192 wherein at least one of the alignment devices comprises cam blocks, and wherein an inner surface of each of the engaging plates includes sloped tracks formed therein, the sloped tracks being configured such that the motion of the cam blocks causes at least one of the first height and the second height to vary during use.

The spinal implant of claim 192 wherein the inner surfaces of the engaging plates include arcuate

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201. The spinal implant of claim 192 wherein at least one of the alignment devices comprises cam blocks, and wherein an inner surface of each of the engaging plates includes sloped tracks formed therein, the sloped tracks being configured such that the motion of the cam blocks causes at least one of the first height and the second height to vary during use, and wherein each of the cam blocks comprises an upper surface and a lower surface, the upper surface and the lower surface being sloped to conform to the sloped tracks in the inner surfaces of the engaging plates.

202. The spinal implant of claim 201 wherein the surfaces of the cam blocks and the sloped tracks in the inner surfaces of the engaging plates are configured such that movement of the cam blocks toward the exterior of the spinal implant increases at least one of the first height and the second height during use and such that movement of the cam blocks away from the exterior of the spinal implant decreases the height between the at least one of the first height and the second height during use.

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- 203. The spinal implant of claim 201 wherein the surfaces of the cam blocks and the sloped tracks in the inner surfaces of the engaging plates are configured such that movement of the cam blocks toward the exterior of the spinal implant decreases at least one of the first height and the second height during use and such that movement of the cam blocks away from the exterior of the spinal implant increases the at least one of the first height and the second height during use.
- The spinal implant of claim 197 wherein the spinal implant comprises a biocompatible material selected from the group consisting of ceramic, metal, polymer, and composite material.
- 205. The spinal implant of claim 197 wherein the engaging plates are substantially planar so as to inhibit subsidence of the vertebrae during use.
- 206. The spinal implant of claim 197 wherein the engaging plates comprise a plurality of openings to allow bone growth to occur through the engaging plates during use.
  - 207. The spinal implant of claim 197, further comprising bone graft material packed between the engaging plates, wherein the engaging plates comprise a plurality of openings to allow bone growth to occur through the engaging plates during use.
  - 208. The spinal implant of claim 197, further comprising protrusions extending from at least one of the engaging plates for enhancing an engagement between the spine and the spinal implant during use.
- The spinal implant of claim 197, further comprising protrusions extending from at least one of the engaging plates for enhancing an engagement between the spine and the spinal implant during use, the protrusions being adapted to extend into the spine.
  - 210. The spinal implant of claim 197, further comprising bone graft material and a retaining plate, the bone graft material being packed between the engaging plates, the retaining plate being configured to keep the bone graft material between the engaging plates during use.

The spinal implant of claim 197 wherein at least one of the engaging plates comprises a face and openings extending through the face to allow bone growth to occur through the engaging plate during use, the openings having a total area that is greater than about 50 percent of a total surface area of the face.

- The spinal implant of claim 197 wherein at least one of the engaging plates comprises a face and openings extending through the face to allow bone growth to occur through the engaging plate during use, the openings having a total area that is between about 60 percent and about 80 percent of a total surface area of the face.
- 10-213. The spinal implant of claim 197 wherein an end of each of the substantially elongated members includes an indentation, and wherein a tip of an adjusting tool may be inserted into the indentation such that movement of the adjusting tool causes the substantially elongated member including the indentation to move.
- The spinal implant of claim 213 wherein the adjusting tool comprises a tool selected from the group consisting of screwdrivers and allen wrenches.
  - 215. A spinal implant for facilitating a fusion between neighboring vertebrae of a spine, comprising:
- a pair of engaging plates configured to fit between and engage the vertebrae to maintain a disk space

  between the vertebrae during use;

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- a first cam block configured to be coupled to inner surfaces of the engaging plates during use;
- a second cam block configured to be coupled to the inner surfaces of the engaging plates during use;
- a first screw configured to be coupled to the first cam block during use, wherein the first screw is configured such that rotation of the first screw in a first angular direction moves the first cam block such that a first height between the engaging plates is substantially increased during use, and wherein the first screw is configured such that rotation of the first screw in a direction opposite to the first angular direction moves the first cam block such that the first height between the engaging plates is substantially decreased during use; and
- a second screw configured to be coupled to the second cam block during use, wherein the second screw is configured such that rotation of the second screw in a second angular direction moves the second cam block such that a second height between the engaging plates is substantially increased during use, and wherein the second screw is configured such that rotation of the second screw in a direction opposite to the second angular direction moves the second cam block such that the second height between the engaging plates is substantially decreased during use.

The spinal implant of claim 215 wherein the first height varies between a first location proximate one of the edges and a second location proximate the edge opposite the one of the edges such that the first height proximate the first location is in the range from less than about the first height proximate the second location to greater than about the first height proximate the second location and wherein the second height varies between a third location proximate another of the edges and a fourth location proximate the edge opposite the another of the edges such that the second height proximate the third location is in the range from less than about the second height proximate the fourth location to greater than about the second height proximate the fourth location.

- 10 217. The spinal implant of claim 215 wherein the first screw is oriented substantially perpendicular to the second screw.
  - 218. The spinal implant of claim 215 wherein the first screw is oriented substantially parallel to the second screw.
  - 219. The spinal implant of claim 218, further comprising:

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- a third cam block configured to be coupled to the inner surfaces of the engaging plates during use;
  - a fourth cam block configured to be coupled to the inner surfaces of the engaging plates during use;
- and wherein the first screw is configured to be coupled to the third cam block such that rotation of the first screw in the first angular direction moves the third cam block such that such that the first height between the engaging plates is substantially increased during use, and wherein the first screw is configured such that rotation of the first screw in the direction opposite to the first angular direction moves the third cam block such that the first height between the engaging plates is substantially decreased during use;
- and wherein the second screw is configured such that rotation of the second screw in the second angular direction moves the fourth cam block such that the second height between the engaging plates is substantially increased during use, and wherein the second screw is configured such that rotation of the second screw in a direction opposite to the second angular direction moves the fourth cam block such that the second height between the engaging plates is substantially decreased during use.
- 35 220. The spinal implant of claim 215 wherein the first screw and the second screw are oriented along a common axis of rotation.
  - 221. A spinal implant for facilitating fusion between neighboring vertebrae of a spine, comprising:

edges;

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a pair of engaging plates configured to fit between and engage the vertebrae to maintain a disk space between the vertebrae during use;

a first cam block configured to be coupled to inner surfaces of the engaging plates during use;

a second cam block configured to be coupled to inner surfaces of the engaging plates during use;

a third cam block configured to be coupled to inner surfaces of the engaging plates during use;

a first screw comprising a first length and configured to be coupled to the first cam block during use, wherein the first screw is configured such that rotation of the first screw in a first angular direction moves the first cam block such that a first height between the engaging plates is substantially increased during use, and wherein the first screw is configured such that rotation of the first screw in a direction opposite to the first angular direction moves the first cam block such that the first height between the engaging plates is substantially decreased during use;

a second screw comprising a second length and configured to be coupled to the second cam block during use, wherein the second screw is configured such that rotation of the second screw in a second angular direction moves the second cam block such that a second height between the engaging plates is substantially increased during use, and wherein the second screw is configured such that rotation of the second screw in a direction opposite to the second angular direction moves the second cam block such that the second height between the engaging plates is substantially decreased during use; and

a third screw comprising a third length and configured to be coupled to the third cam block during use, wherein the third screw is configured such that rotation of the third screw in a third angular direction moves the third cam block such that a third height between the engaging plates is substantially increased during use, and wherein the third screw is configured such that rotation of the third screw in a direction opposite to the third angular direction moves the third cam block such that the third height between the engaging plates is substantially decreased during use.

222. The spinal implant of claim 221 wherein the first screw and the second screw are oriented such that they share a common axis of rotation, the third screw being oriented substantially perpendicular to the first screw and the second screw.

223. The spinal implant of claim 221 wherein the first screw and the second screw are oriented substantially perpendicular to one another, the third screw being oriented substantially at a first obtuse angle to the first screw and substantially at a second obtuse angle to the second screw.

- The spinal implant of claim 221 wherein the first screw is oriented substantially perpendicular to an edge of the spinal implant, the second screw being oriented substantially perpendicular to the first screw, the third screw being oriented substantially perpendicular to the second screw, the third screw sharing a common axis of rotation with the first screw.
- 10 225. The spinal implant of claim 221 wherein the first screw is oriented substantially perpendicular to an edge of the spinal implant, the second screw being oriented substantially perpendicular to the first screw, the third screw being oriented substantially at a first obtuse angle to the first screw and at a second obtuse angle to the second screw.
- 15 226. The spinal implant of claim 221 wherein the first screw is oriented substantially perpendicular to an edge of the spinal implant, the second screw being oriented substantially at a first obtuse angle to the first screw, the third screw being oriented substantially at a second obtuse angle to the first screw.
  - 227. The spinal implant of claim 221 wherein the first screw is oriented substantially parallel to and substantially adjacent one of the edges, and wherein the second screw is oriented substantially parallel to and substantially adjacent the edge opposite the one of the edges, and wherein the third screw is oriented substantially parallel to and substantially between the first screw and the second screw.
  - 228. The spinal implant of claim 221 wherein the first height varies along the first length and wherein the second height varies along the second length and wherein the third height varies along the third length.
    - 229. A spinal implant for facilitating a fusion between neighboring vertebrae of a spine, comprising:
      - a first side edge located opposite a second side edge;

an anterior edge located opposite a posterior edge;

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a pair of engaging plates configured to fit between and engage the vertebrae to maintain a disk space between the vertebrae during use, the engaging plates each comprising a length substantially between the anterior and posterior edges, the engaging plates each comprising a width substantially between the first side edge and the second side edge;

a first alignment device positionable between the engaging plates and capable of separating the engaging plates at a first location proximate the anterior edge during use;

a second alignment device positionable between the engaging plates and capable of separating the engaging plates at a second location proximate the posterior edge during use;

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a third alignment device positionable between the engaging plates and capable of separating the engaging plates at a third location proximate the first side edge during use; and

a fourth alignment device positionable between the engaging plates and capable of separating the engaging plates at a fourth location proximate the second side edge during use; and

wherein the first and second alignment devices are independently operable of one another during use to substantially maintain a first height between the engaging plates along a direction substantially from the anterior edge to the posterior edge, thereby substantially maintaining a natural curvature of the spine during use; and

wherein the third and fourth alignment devices are independently operable of one another during use to substantially maintain a second height between the engaging plates along a direction substantially from the first side edge to the second side edge, thereby substantially maintaining a natural position of the spine during use.

- 230. The spinal implant of claim 229 wherein the first and second alignment devices are independently adjustable such that the first height varies between the first location and the second location such that the first height proximate the first location is in the range from less than about the first height proximate the second location to greater than about the first height proximate the second location.
- 231. The spinal implant of claim 229 wherein the third and fourth alignment devices are independently adjustable such that the second height varies between the third location and the fourth location such that the second height proximate the third location is in the range from less than about the second height proximate the fourth location to greater than about the second height proximate the fourth location.
- The spinal implant of claim 229 wherein the first and second alignment devices are independently adjustable such that the first height varies between the first location and the second location such that the first height proximate the first location is in the range from less than about the first height proximate the second location to greater than about the first height proximate the second location and wherein the third and fourth alignment devices are independently adjustable such that the second height varies between the third location and the fourth location such that the second height proximate the third location is in the range from less than

about the second height proximate the fourth location to greater than about the second height proximate the fourth location.

233. A spinal implant for facilitating fusion between neighboring vertebrae of a spine, comprising:

edges;

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an pair of engaging plates configured to fit between and engage the vertebrae to maintain a disk space between the vertebrae during use;

a first cam block configured to be coupled to inner surfaces of the engaging plates during use;

a second cam block configured to be coupled to inner surfaces of the engaging plates during use;

a third cam block configured to be coupled to inner surfaces of the engaging plates during use;

a fourth cam block configured to be coupled to inner surfaces of the engaging plates during use;

a first screw configured to be coupled to the first cam block during use, wherein the first screw is configured such that rotation of the first screw in a first angular direction moves the first cam block such that a first height between the engaging plates is substantially increased during use, and wherein the first screw is configured such that rotation of the first screw in a direction opposite to the first angular direction moves the first cam block such that the first height between the engaging plates is substantially decreased during use;

a second screw configured to be coupled to the second cam block during use, wherein the second screw is configured such that rotation of the second screw in a second angular direction moves the second cam block such that a second height between the engaging plates is substantially increased during use, and wherein the second screw is configured such that rotation of the second screw in a direction opposite to the second angular direction moves the second cam block such that the second height between the engaging plates is substantially decreased during use;

a third screw configured to be coupled to the third cam block during use, wherein the third screw is configured such that rotation of the third screw in a third angular direction moves the third cam block such that a third height between the engaging plates is substantially increased during use, and wherein the third screw is configured such that rotation of the third screw in a direction opposite to the third angular direction moves the third cam block such that the third height between the engaging plates is substantially decreased during use; and

a fourth screw configured to be coupled to the fourth cam block during use, wherein the fourth screw is configured such that rotation of the fourth screw in a fourth angular direction moves the fourth cam block such that a fourth height between the engaging plates is substantially increased during use, and wherein the fourth screw is configured such that rotation of the fourth screw in a direction opposite to the fourth angular direction moves the fourth cam block such that the fourth height between the engaging plates is substantially decreased during use.

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- 234. The spinal implant of claim 233 wherein the first screw and the second screw are aligned along a first common axis of rotation, the third screw and the fourth screw being aligned along a second common axis of rotation intersecting the first common axis of rotation.
- 235. The spinal implant of claim 233 wherein the first screw and the second screw are aligned along a first common axis of rotation substantially perpendicular to an edge of the spinal implant, the third screw and the fourth screw being aligned along a second common axis of rotation substantially perpendicular to the first common axis of rotation.
- 236. The spinal implant of claim 233 wherein the first screw and the second screw are aligned along a first common axis of rotation substantially parallel to and substantially adjacent one of the edges of the spinal implant, the third screw and the fourth screw being aligned along a second common axis of rotation substantially parallel to and substantially adjacent another of the edges opposite the one of the edges.
- 237. The spinal implant of claim 233, further comprising a bracket assembly separating the engaging plates during use, wherein the bracket assembly supports each of the screws during use.
- 25 238. The spinal implant of claim 233 wherein the bracket assembly comprises ends including arcuate grooves configured to conform to a curvature of the screws.
  - 239. The spinal implant of claim 233 wherein the inner surfaces of the engaging plates include arcuate grooves configured to conform to a curvature of the screws.
  - 240. The spinal implant of claim 233, further comprising a stationary block situated between the engaging plates during use, wherein the stationary block engages the first screw such that coupling is maintained between the first screw and the first cam block during use, and wherein the stationary block engages the second screw such that coupling is maintained between the second screw and the second cam block during use, and wherein the stationary block engages the third screw such that coupling is maintained between the third screw and the third cam block during use, and wherein the stationary block engages the fourth screw such that coupling is maintained between the fourth screw and the fourth cam block during use.

241. The spinal implant of claim 233 wherein at least one of the alignment devices comprises cam blocks, and wherein an inner surface of each of the engaging plates includes sloped tracks formed therein, the sloped tracks being configured such that the motion of the cam blocks during use causes a height between the engaging plates to vary.

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242. The spinal implant of claim 233 wherein at least one of the alignment devices comprises cam blocks, and wherein an inner surface of each of the engaging plates includes sloped tracks formed therein, the sloped tracks being configured such that the motion of the cam blocks during use causes a height between the engaging plates to vary, and wherein each of the cam blocks comprises an upper surface and a lower surface, the upper surface and the lower surface being sloped to conform to the sloped tracks in the inner surfaces of the engaging plates.

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The spinal implant of claim 242 wherein the surfaces of the cam blocks and the sloped tracks in the inner surfaces of the engaging plates are configured such that movement of the cam blocks toward the exterior of the spinal implant increases a height between the engaging plates and such that movement of the cam blocks away from the exterior of the spinal implant decreases the height between the engaging plates.

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The spinal implant of claim 242 wherein the surfaces of the cam blocks and the sloped tracks in the 244. inner surfaces of the engaging plates are configured such that movement of the cam blocks toward the exterior of the spinal implant decreases a height between the engaging plates and such that movement of the cam blocks away from the exterior of the spinal implant increases the height between the engaging plates.

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245. The spinal implant of claim 233 wherein the spinal implant comprises a biocompatible material selected from the group consisting of ceramic, metal, polymer, and composite material.

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the engaging plates during use.

246. The spinal implant of claim 233 wherein the engaging plates are substantially planar so as to inhibit subsidence of the vertebrae during use.

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247. The spinal implant of claim 233 wherein the engaging plates comprise a plurality of openings to allow bone growth to occur through the engaging plates during use.

The spinal implant of claim 233, further comprising bone graft material packed between the engaging

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249. The spinal implant of claim 233, further comprising protrusions extending from at least one of the engaging plates for enhancing an engagement between the spine and the spinal implant during use.

plates, wherein the engaging plates comprise a plurality of openings to allow bone growth to occur through

250. The spinal implant of claim 233, further comprising protrusions extending from at least one of the engaging plates for enhancing an engagement between the spine and the spinal implant during use, the protrusions being adapted to extend into the spine.

- The spinal implant of claim 233, further comprising bone graft material and a retaining plate, the bone graft material being packed between the engaging plates, the retaining plate being configured to keep the bone graft material between the engaging plates during use.
  - 252. The spinal implant of claim 233 wherein at least one of the engaging plates comprises a face and openings extending through the face to allow bone growth to occur through the engaging plate during use, the openings having a total area that is greater than about 50 percent of a total surface area of the face.

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- 253. The spinal implant of claim 233 wherein at least one of the engaging plates comprises a face and openings extending through the face to allow bone growth to occur through the engaging plate during use, the openings having a total area that is between about 60 percent and about 80 percent of a total surface area of the face.
- 254. The spinal implant of claim 233 wherein an end of each of the substantially elongated members includes an indentation, and wherein a tip of an adjusting tool may be inserted into the indentation such that movement of the adjusting tool causes the substantially elongated member including the indentation to move.
- 255. The spinal implant of claim 254 wherein the adjusting tool comprises a tool selected from the group consisting of screwdrivers and allen wrenches.
- 256. A method for facilitating a fusion between neighboring vertebrae of a spine, comprising:
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   inserting a spinal implant between the vertebrae, the spinal implant comprising:
   edges;
  - a pair of engaging plates for engaging the vertebrae that extend substantially between the edges;
  - a first alignment device located between the engaging plates for separating the engaging plates; and
  - a second alignment device located between the engaging plates for separating the engaging plates;
  - adjusting the first alignment device to adjust a first height between the engaging plates at a first location; and

adjusting the second alignment device to adjust a second height between the engaging plates at a second location; and

wherein the first and second alignment devices are adjusted independently of one another such that

the first differs from the second height so as to maintain the spine in a substantially natural position.

257. A method for facilitating a fusion between neighboring vertebrae of a spine, comprising: inserting a spinal implant between the vertebrae, the spinal implant comprising:

edges;

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a pair of engaging plates extending substantially between the edges, the engaging plates each comprising an inner surface and a substantially elongated track formed into the inner surface; and

an alignment device located between the engaging plates and comprising a cam block and a substantially elongated member;

moving the substantially elongated member to move the cam block along the tracks, wherein movement of the cam block causes a change in height between the engaging plates; and

adjusting the height between the engaging plates such that the height at a first location differs from the height at a second location opposite the first location, thereby maintaining the spine in a substantially natural position.

258. A method for facilitating a fusion between neighboring vertebrae of a human spine, comprising:

inserting a spinal implant between the vertebrae, the spinal implant comprising a pair of engaging plates for engaging the vertebrae and a turnbuckle threaded through a pair of opposed cam blocks such that the cam blocks contact a region of the engaging plates; and

rotating the turnbuckle to move the cam blocks relative to each other, thereby altering a height between the engaging plates to maintain a substantially natural curvature of the spine.

259. The method of claim 258, further comprising packing bone graft material between the engaging plates, the engaging plates comprising a plurality of openings to allow bone growth to occur through the engaging plates.

260. The method of claim 258, further comprising packing bone graft material between the engaging plates and placing a retaining plate across a gap between the engaging plates, the engaging plates comprising a plurality of openings to allow bone growth to occur through the engaging plates.

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- 261. The method of claim 258 wherein rotating the turnbuckle comprises:
  - engaging an end of the turnbuckle with an adjusting tool; and moving the adjusting tool such that the turnbuckle rotates.

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- 262. The method of claim 261 wherein the adjusting tool comprises a tool selected from the group consisting of screwdrivers and allen wrenches.
- 263. A method for facilitating a fusion between neighboring vertebrae of a human spine, comprising:

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inserting a spinal implant between the vertebrae, the spinal implant comprising (a) a pair of engaging plates configured to fit between and make contact with the vertebrae, (b) a first turnbuckle threaded through a first pair of opposed cam blocks such that the first pair of opposed cam blocks contact the engaging plates at a first region, and (c) a second turnbuckle threaded through a second pair of opposed cam blocks such that the second pair of opposed cam blocks contact the engaging plates at a second region; and

rotating at least one of the turnbuckles to move at least one of the pairs of opposed cam blocks, thereby altering a height between the engaging plates to maintain a substantially natural curvature of the spine.

- 264. The method of claim 263, further comprising packing bone graft material between the engaging plates, the engaging plates comprising a plurality of openings to allow bone growth to occur through the engaging plates.
- The method of claim 263, further comprising packing bone graft material between the engaging
  plates and placing a retaining plate across a gap between the engaging plates, the engaging plates comprising a plurality of openings to allow bone growth to occur through the engaging plates.
  - 266. The method of claim 263 wherein rotating the turnbuckle comprises:
- engaging an end of the turnbuckle with an adjusting tool; and moving the adjusting tool such that the turnbuckle rotates.

267. The method of claim 266 wherein the adjusting tool comprises a tool selected from the group consisting of screwdrivers and allen wrenches.

268. A method for facilitating a fusion between neighboring vertebrae of a human spine, comprising:

inserting a spinal implant between the vertebrae, the spinal implant comprising (a) a pair of engaging plates configured to fit between and make contact with the vertebrae, (b) a first screw threaded through a first cam block such that the first cam block contacts the engaging plates at a first region, (c) a second screw threaded through a second cam block such that the second cam block contacts the engaging plates at a second region, and (d) a third screw threaded through a third cam block such that the third cam block contacts the engaging plates at a third region; and

rotating at least one of the screws such that at least one of the cam blocks is moved, thereby altering a height between the engaging plates to maintain a substantially natural curvature of the spine.

- 269. The method of claim 268, further comprising packing bone graft material between the engaging plates, the engaging plates comprising a plurality of openings to allow bone growth to occur through the engaging plates.
- 20 270. The method of claim 268, further comprising packing bone graft material between the engaging plates and placing a retaining plate across a gap between the engaging plates, the engaging plates comprising a plurality of openings to allow bone growth to occur through the engaging plates.
  - 271. The method of claim 268 wherein rotating the turnbuckle comprises:

engaging an end of the turnbuckle with an adjusting tool; and moving the adjusting tool such that the turnbuckle rotates.

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- 30 272. The method of claim 271 wherein the adjusting tool comprises a tool selected from the group consisting of screwdrivers and allen wrenches.
  - 273. A method for facilitating a fusion between neighboring vertebrae of a human spine, comprising:

inserting a spinal implant between the vertebrae, the spinal implant comprising (a) a pair of engaging plates configured to fit between and make contact with the vertebrae, (b) a first screw threaded through a first cam block such that the first cam block contacts the engaging plates at a first region, (c) a second screw threaded through a second cam block such that the second cam block contacts the engaging plates at a second

region, (d) a third screw threaded through a third cam block such that the third cam block contacts the engaging plates at a third region, and (e) a fourth screw threaded through a fourth cam block such that the fourth cam block contacts the engaging plates at a fourth region; and

- rotating at least one of the screws such that at least one of the cam blocks is moved, thereby altering a height between the engaging plates to maintain a substantially natural curvature of the spine.
  - 274. The method of claim 273, further comprising packing bone graft material between the engaging plates, the engaging plates comprising a plurality of openings to allow bone growth to occur through the engaging plates.
  - 275. The method of claim 273, further comprising packing bone graft material between the engaging plates and placing a retaining plate across a gap between the engaging plates, the engaging plates comprising a plurality of openings to allow bone growth to occur through the engaging plates.
  - 276. The method of claim 273 wherein rotating the turnbuckle comprises:

engaging an end of the turnbuckle with an adjusting tool; and

- moving the adjusting tool such that the turnbuckle rotates.
- 277. The method of claim 276 wherein the adjusting tool comprises a tool selected from the group consisting of screwdrivers and allen wrenches.
- 25 278. A method for facilitating a fusion between neighboring vertebrae of a spine, comprising:

inserting a first spinal implant between the vertebrae at a first location, the first spinal implant comprising:

first edges;

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- a first pair of engaging plates extending substantially between the first edges, the first engaging plates each comprising an inner surface and a substantially elongated track formed into the inner surface; and
- a first alignment device located between the first engaging plates and comprising a first cam block and a first substantially elongated member;

inserting a second spinal implant between the vertebrae at a second location, the second spinal implant comprising:

second edges;

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a second pair of engaging plates extending substantially between the second edges, the second engaging plates each comprising an inner surface and a substantially elongated track formed into the inner surface; and

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a second alignment device located between the second engaging plates and comprising a second cam block and a second substantially elongated member;

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moving the first substantially elongated member to move the first cam block along the tracks in the first engaging plates, wherein movement of the first cam block causes a change in a first height between the first engaging plates;

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moving the second substantially elongated member to move the second cam block along the tracks in the second engaging plates, wherein movement of the second cam block causes a change in a second height between the second engaging plates; and

adjusting the first height and the second height to maintain the spine in a substantially natural position.

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279. A method for facilitating a fusion between neighboring vertebrae of a human spine, comprising:

inserting a first spinal implant between the vertebrae, the first spinal implant comprising a first pair of engaging plates for engaging the vertebrae and a first turnbuckle threaded through a first pair of opposed cam blocks such that the first cam blocks contact a region of the first engaging plates;

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inserting a second spinal implant between the vertebrae, the second spinal implant comprising a second pair of engaging plates for engaging the vertebrae and a second turnbuckle threaded through a second pair of opposed cam blocks such that the second cam blocks contact a region of the second engaging plates;

rotating the first turnbuckle to move the cam blocks relative to each other, thereby altering a first

height between the first engaging plates; and

rotating the second turnbuckle to move the second cam blocks relative to each other, thereby altering a second height between the second engaging plates; and

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adjusting the first height and the second height to maintain the spine in a substantially natural position.

- 5 280. The method of claim 279, further comprising packing bone graft material between the first alignment device and the second alignment device.
  - 281. The method of claim 279 wherein rotating one of the turnbuckles comprises:
- engaging an end of one of the turnbuckles with an adjusting tool; and moving the adjusting tool such that the one of the turnbuckles rotates.
- The method of claim 281 wherein the adjusting tool comprises a tool selected from the group consisting of screwdrivers and allen wrenches.

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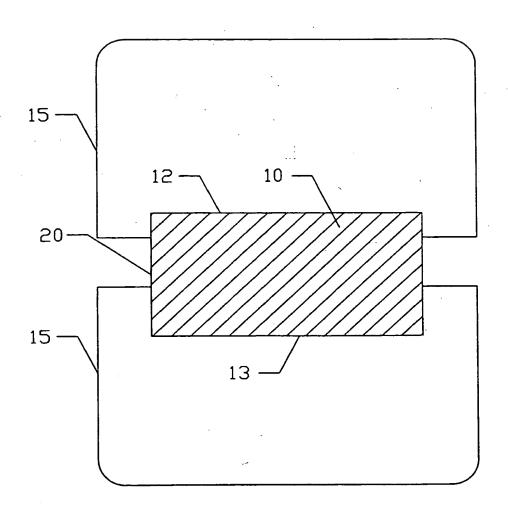


FIG. 1 (PRIOR ART)

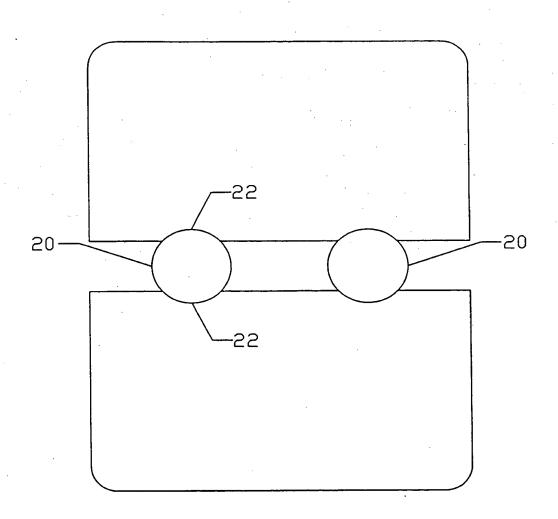


FIG. 2 (PRIOR ART)

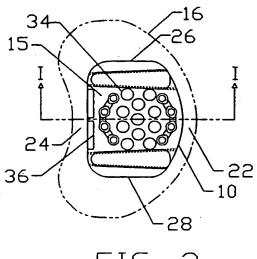


FIG. 3

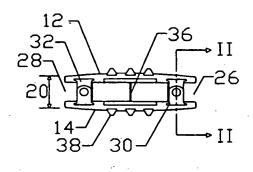


FIG. 5

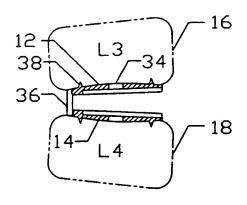


FIG. 4A

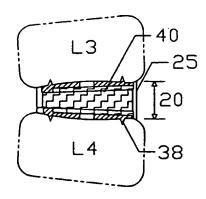


FIG. 4B

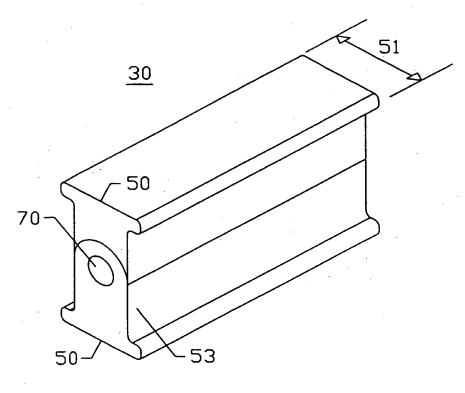


FIG. 6A

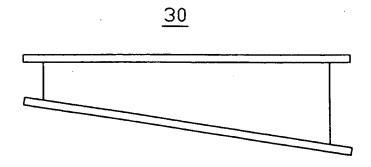


FIG. 6B

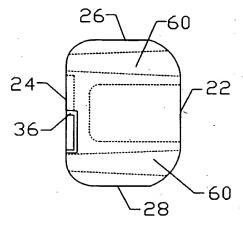


FIG. 7

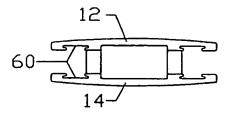


FIG. 8

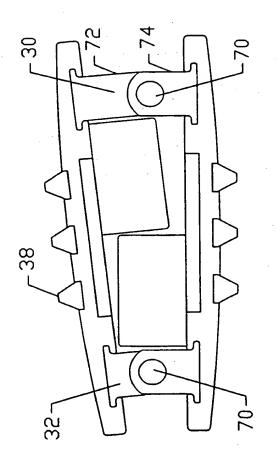
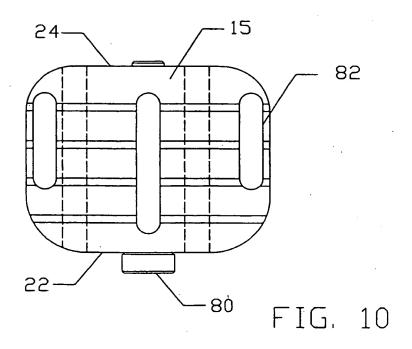
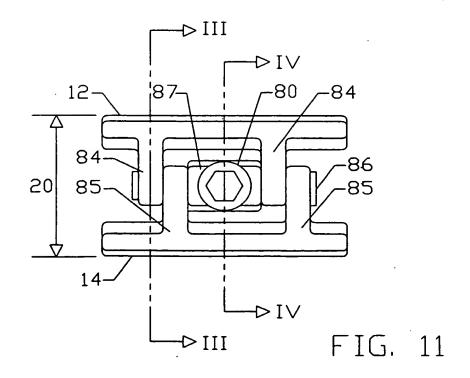
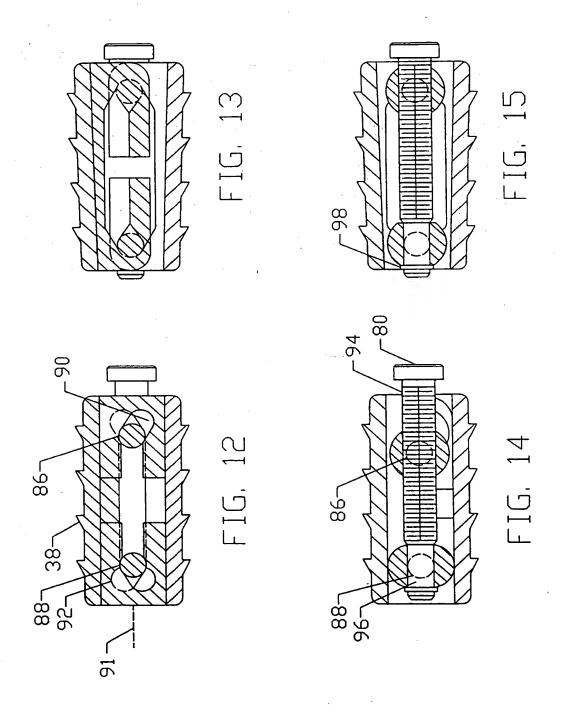


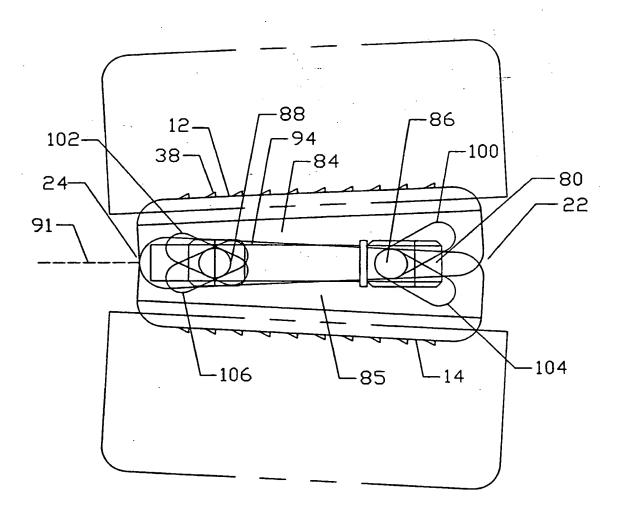
FIG. 9

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FÍG. 16

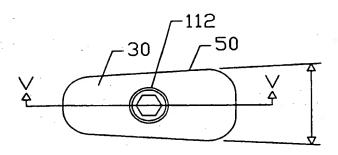
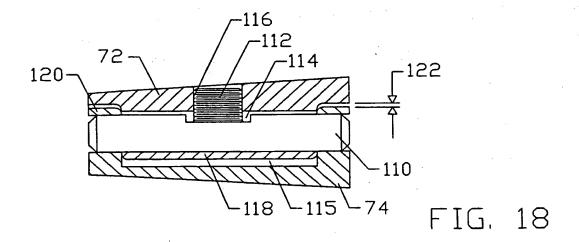


FIG. 17



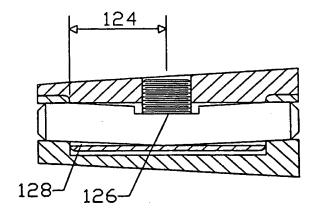
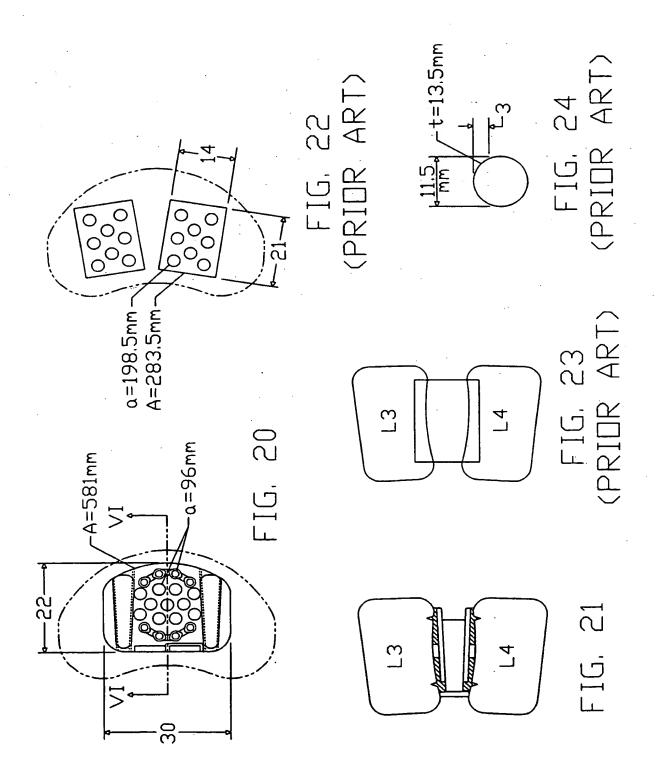
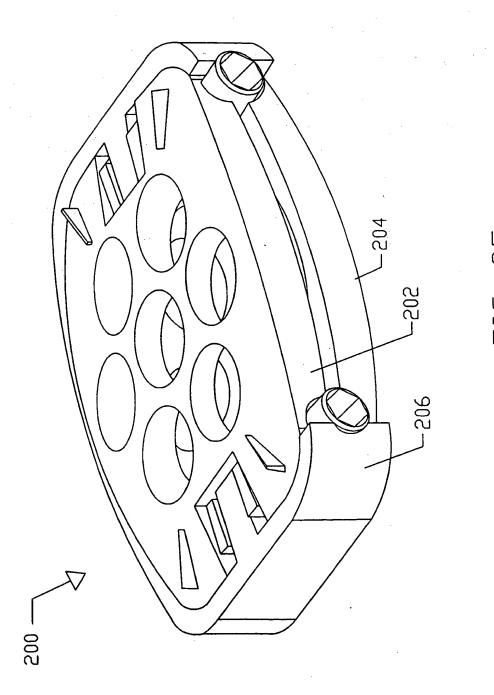


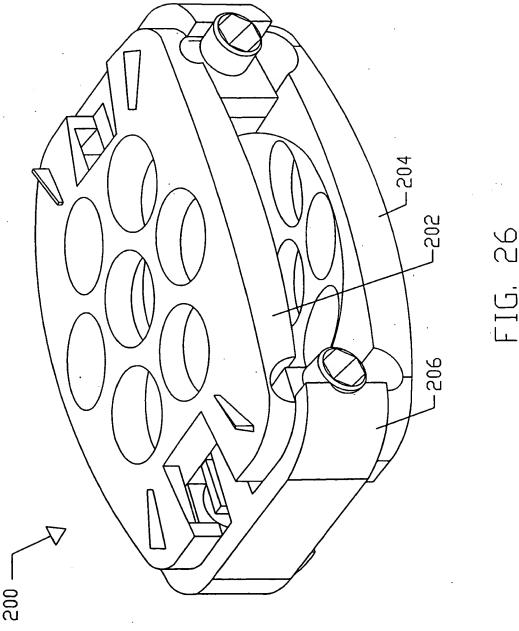
FIG. 19

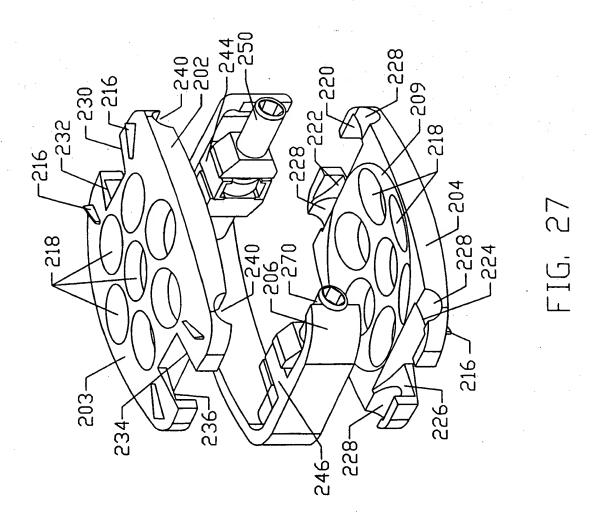
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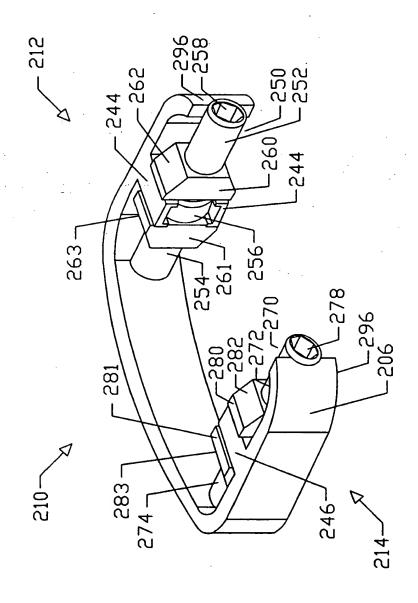
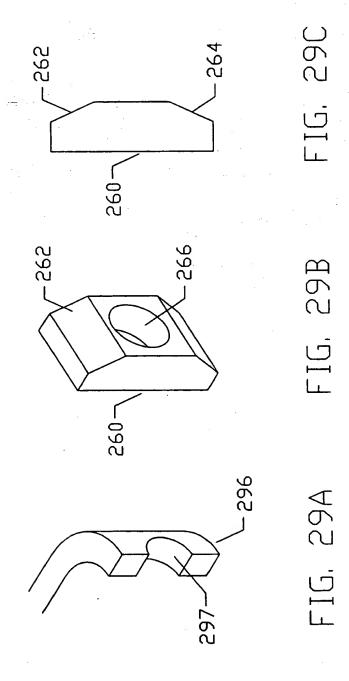
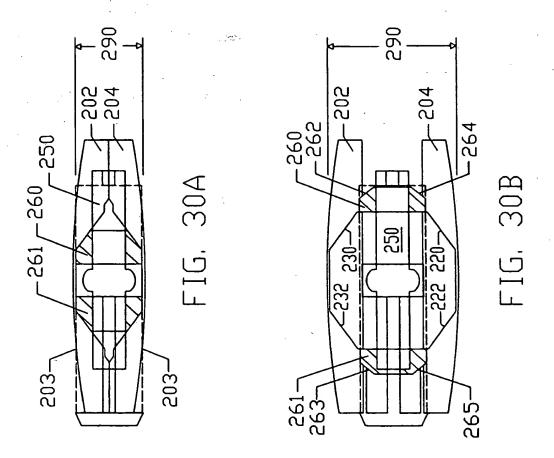
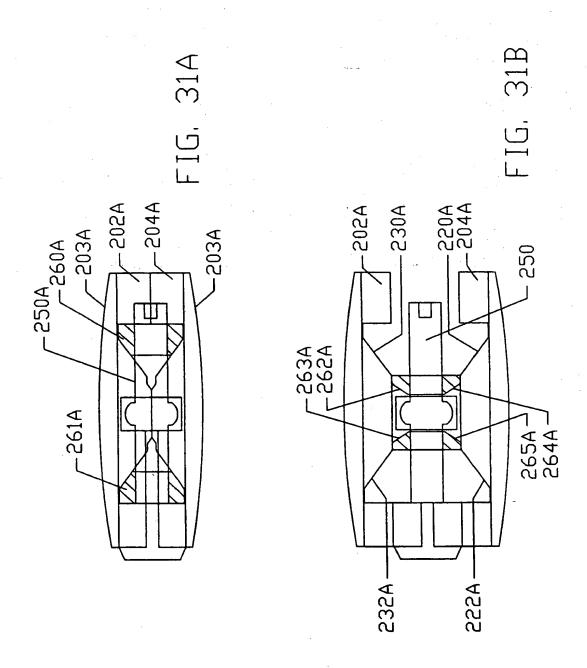


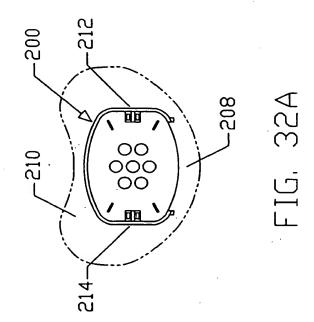
FIG. 28

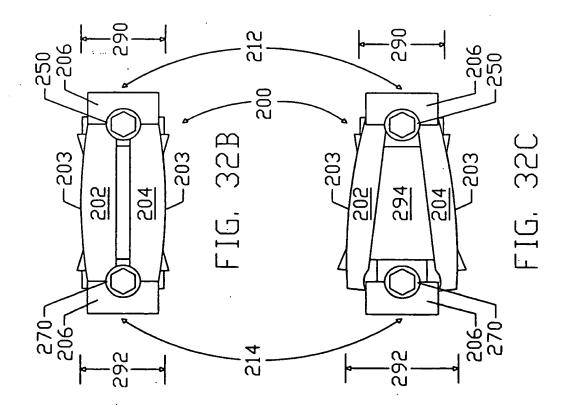


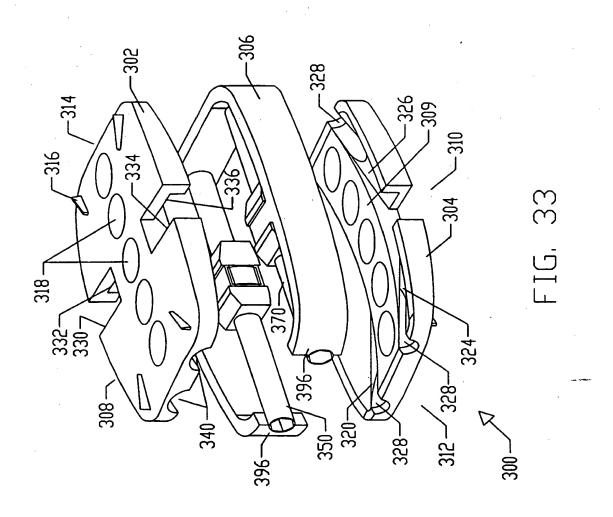


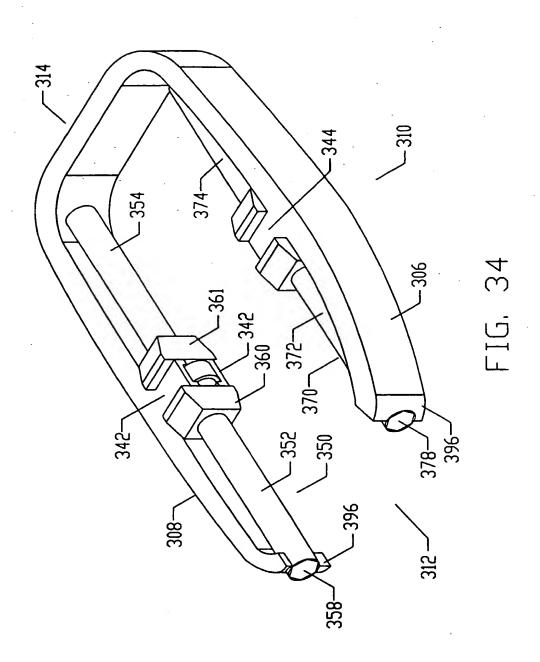


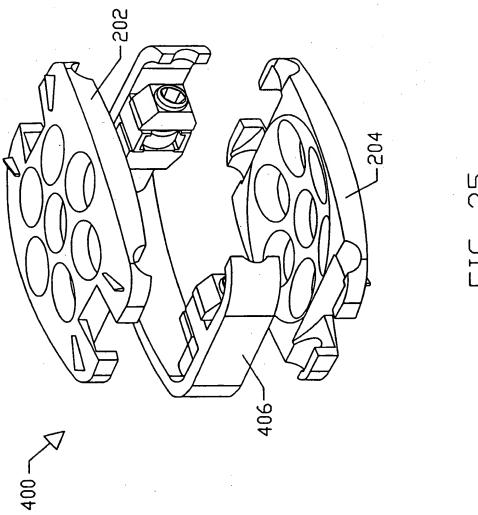
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FIG, 35

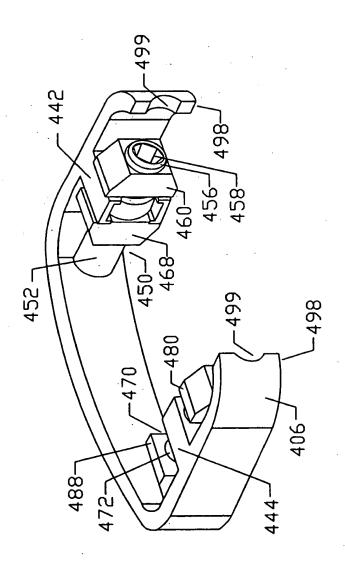
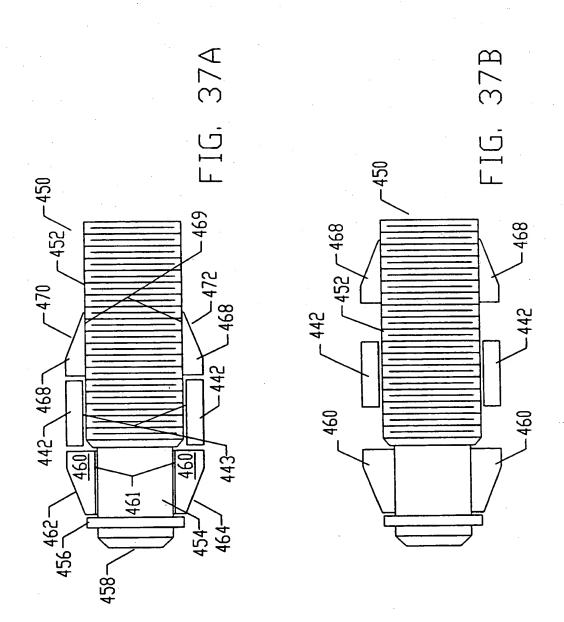
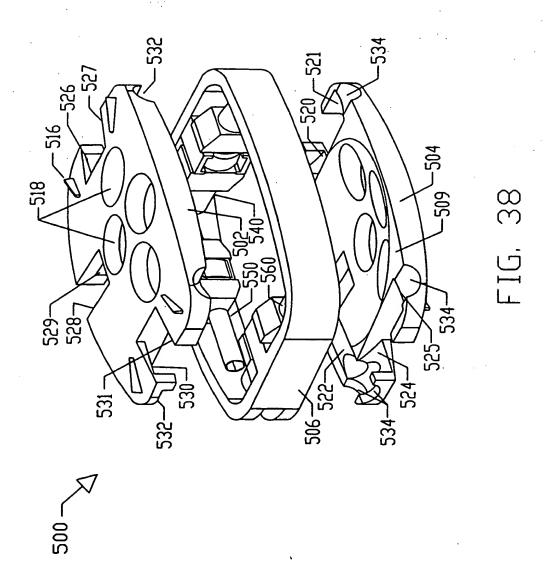
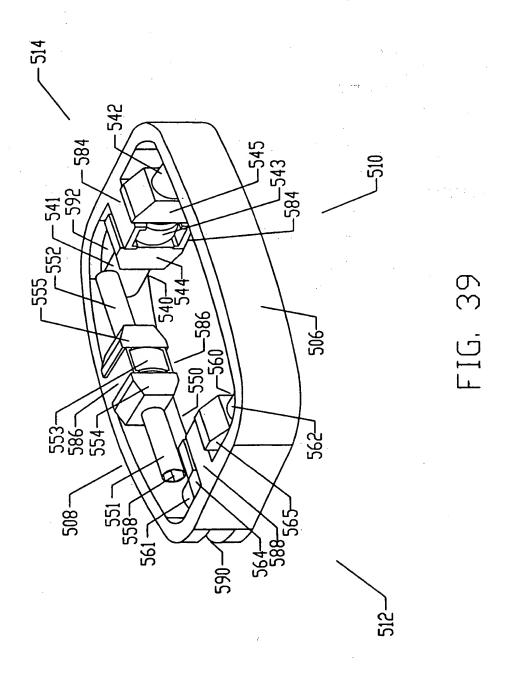


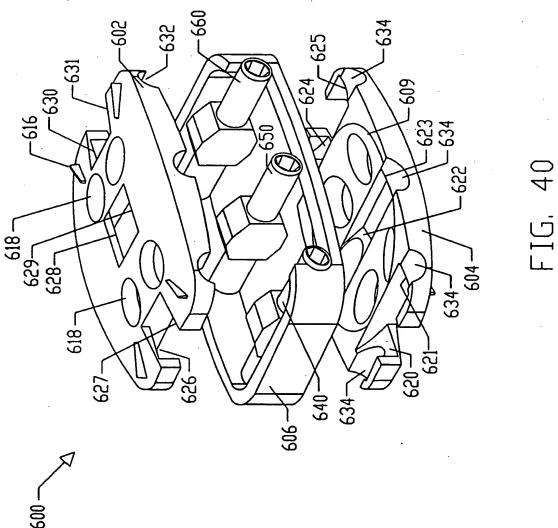
FIG. 36

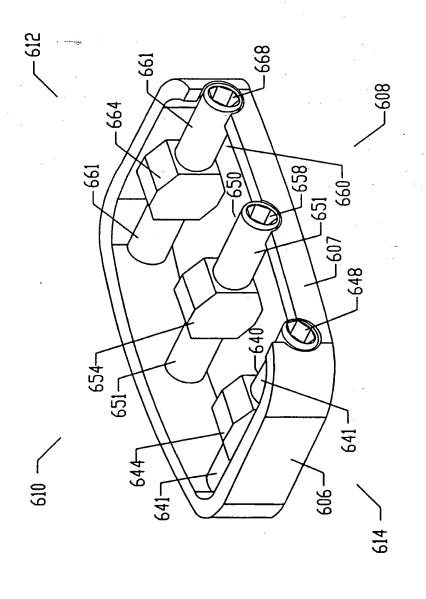
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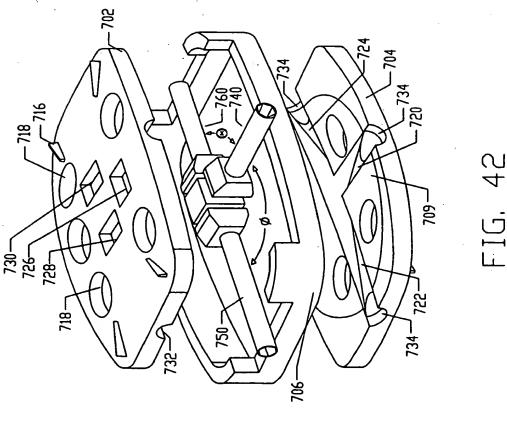








FIG, 41



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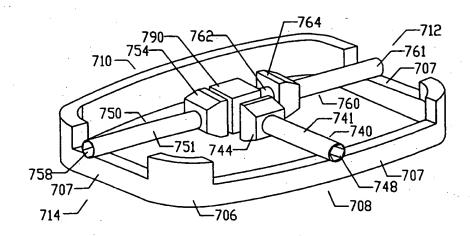


FIG. 43A

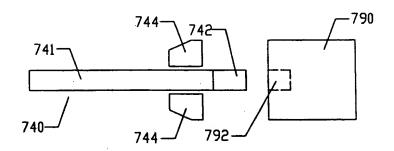
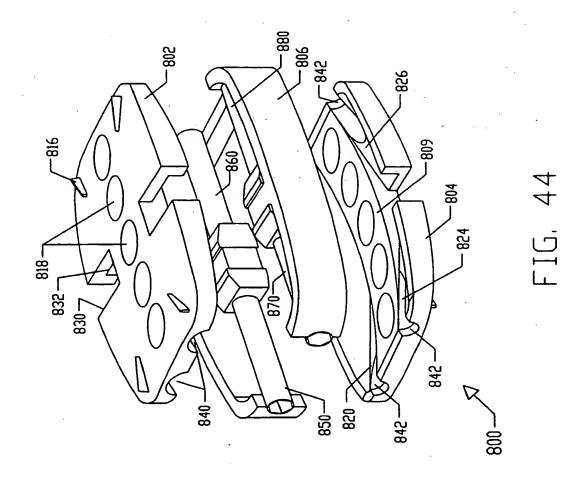
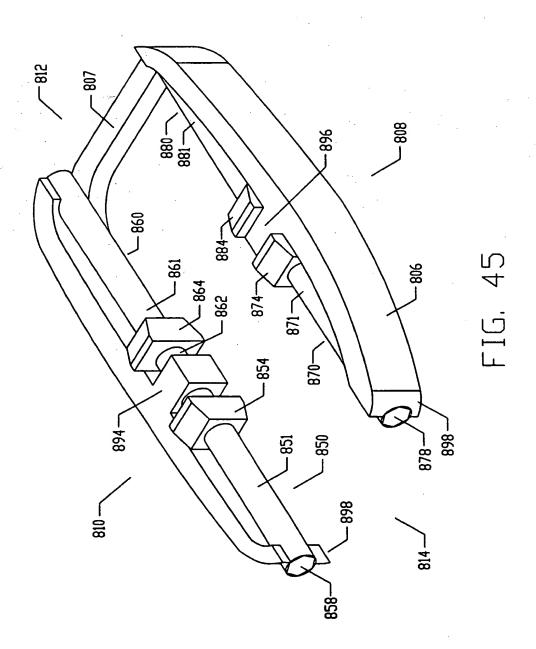
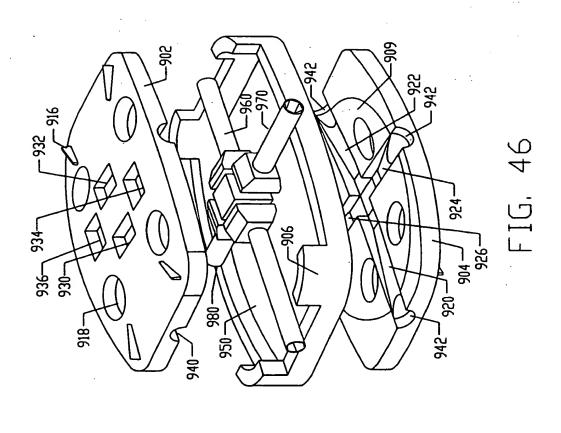


FIG. 43B

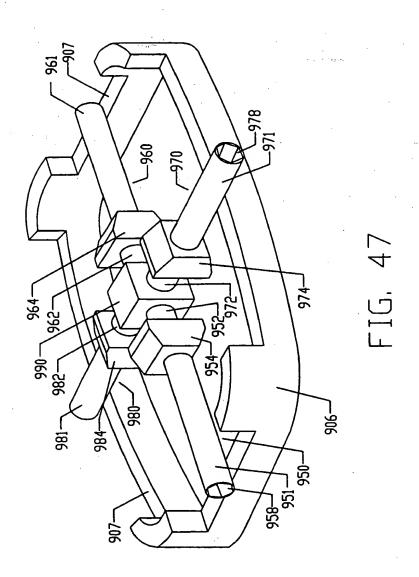




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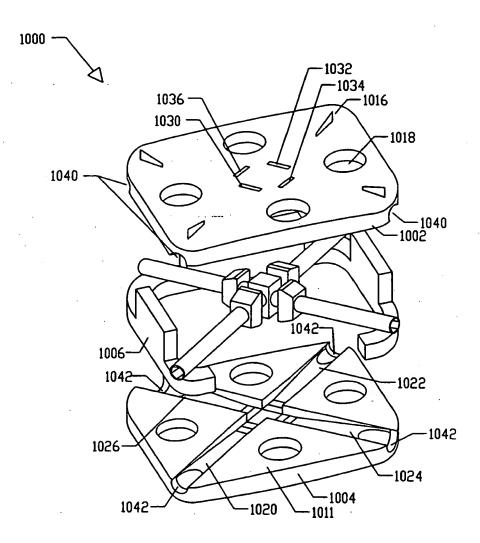
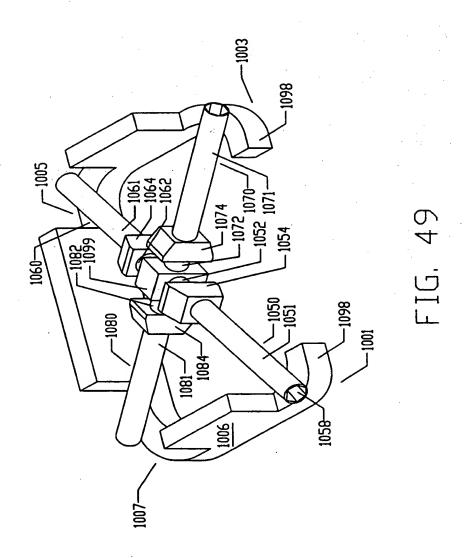


FIG. 48



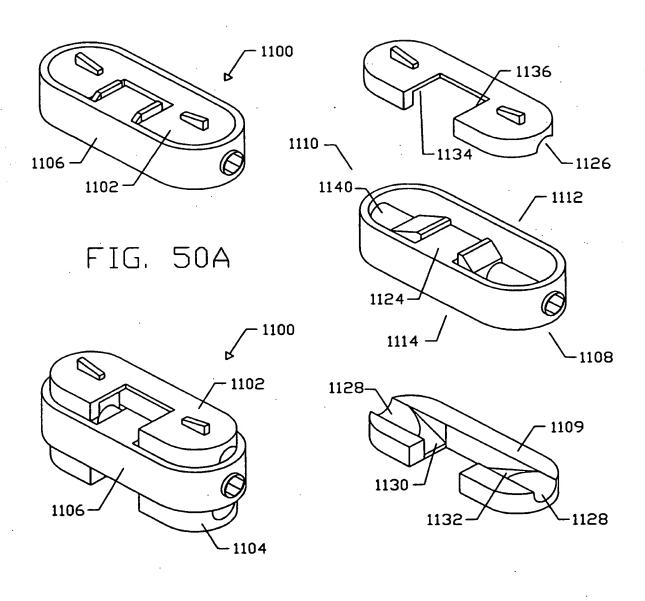
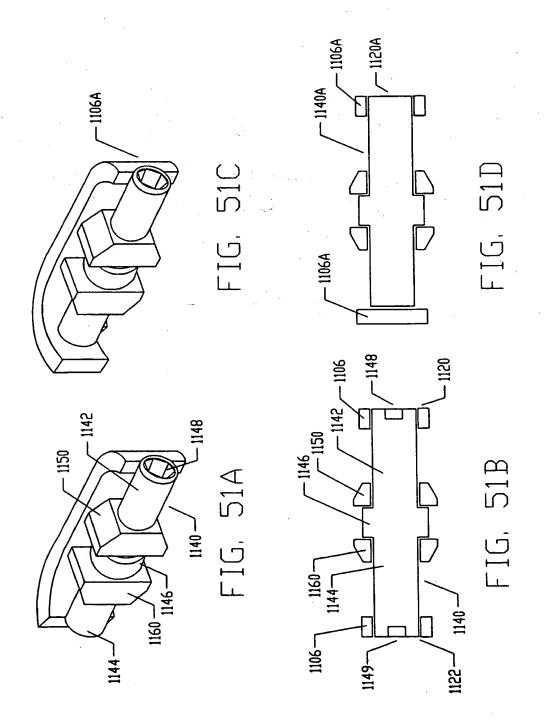


FIG. 50B

FIG. 50C

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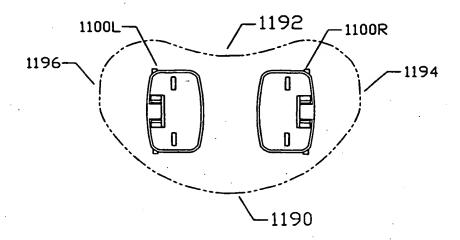


FIG. 52A

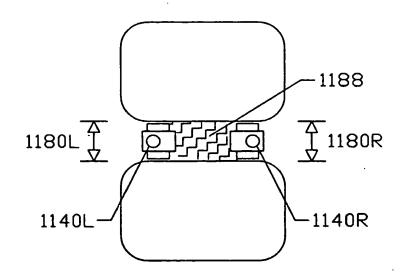


FIG. 52B

#### INTERNATIONAL SEARCH REPORT

Intern. ial Application No PCT/US 98/08832

A. CLASSIF	FICATION OF SUBJECT MATTER A61F2/44			
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	nternational Patent Classification (IPC) or to both national classifica	tion and IPC		
	SEARCHED  cumentation searched (classification system followed by classification	n symbols)		
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Documental	tion searched other than minimum documentation to the extent that su	oh documents are included in the fields sear	ched	
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Electronic d	ata base consulted during the international search (name of data bas	se and, where practical, search terms used)		
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	ENTS CONSIDERED TO BE RELEVANT  Citation of document, with indication, where appropriate, of the rele	went nacranae	Relevant to claim No.	
Category °	Citation of document, with indication, where appropriate, of the rese	want passages	nelevant to claim No.	
х	FR 2 717 068 A (BIOMAT) 15 Septem	mber 1005	1	
Â	see the whole document	ibei 1995	23,63,	
•			74,215,	
			221,229,	
		·	233	
х	WO 97 00054 A (OLERUD) 3 January	1997	1.	
	see the whole document			
A	DE 43 23 956 C (ESKA MEDICAL) 27	October	42,171	
^	1994	octobe!	16,27	
	see the whole document	,		
١,	US 5 522 899 A (MICHELSON) 4 Jun	a 1996	145,167,	
A	cited in the application	e 1990	169,229	
	see the whole document			
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	ther documents are listed in the continuation of box C.	Y Patent family members are listed	- anney	
X Fur	ther googneens are instead in the continuation of cox C.	X Patent family members are listed in		
* Special c	ategories of cited documents :	"T" later document published after the inte		
"A" docum	ent defining the general state of the art which is not dered to be of particular relevance	or priority date and not in conflict with the application but cited to understand the principle or theory underlying the		
'E' earlier	document but published on or after the international	invention  "X" document of particular relevance; the claimed invention		
	ent which may throw doubts on priority claim(s) or	cannot be considered novel or canno involve an inventive step when the do		
	n is cited to establish the publication date of another on or other special reason (as specified)	"Y" document of particular relevance; the cannot be considered to involve an in	claimed invention ventive step when the	
	ment referring to an oral disclosure, use, exhibition or recens	document is combined with one or m ments, such combination being obvio	ore other such doou-	
P' docum	than the priority date claimed	in the art. "&" document member of the same patent		
	a actual completion of the international search	Date of mailing of the international ser		
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3	14 August 1998	0 1. 09. 98		
Name and	mailing address of the ISA	Authorized officer		
	European Patent Office, P.B. 5818 Patentiaan 2 NL - 2280 HV Rijswijk			
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### INTERNATIONAL SEARCH REPORT

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	ation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages		Relevant to claim No.
A	EP 0 260 044 A (SHEPPERD) 16 March 1988 see the whole document		171,175, 192
A	WO 97 06753 A (ZIENTEK) 27 February 1997		
A	SU 1 424 826 A (BELO TRAUMAT ORTHOP) 23 September 1988		·
P,A	US 5 653 763 A (ERRICO) 5 August 1997		
P,A	US 5 665 122 A (KAMBIN) 9 September 1997		
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Inte ational application No. PCT/US 98/08832

#### INTERNATIONAL SEARCH REPORT

Box I	Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)
This Inte	emational Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. X	Claims Nos.: 75-144, 256-282 because they relate to subject matter not required to be searched by this Authority, namely:
·	Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2	Claims Nos.:  because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
з. 🗌	Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box II	Observations where unity of invention is lacking (Continuation of item 2 of first sheet)
1. [	As all required additional search fees were timely paid by the applicant, this International Search Report covers all
2.	As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.	As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.	No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Rema	The additional search fees were accompanied by the applicant's protest.  No protest accompanied the payment of additional search fees.

### INTERNATIONAL SEARCH REPORT

information on patent family members

Intern val Application No PCT/US 98/08832

			101/03	20,00022
Patent document cited in search report		Publication date	Patent family member(s)	Publication date
FR 2717068	Α	15-09-1995	NONE	· · · · · · · · · · · · · · · · · · ·
WO 9700054	Α	03-01-1997	AU 6144496 A	15-01-1997
			SE 9502224 A SE 9503191 A	20-12-1996
			2E 3203131 W	15-03-1997
DE 4323956	C	27-10-1994	EP 0635246 A	25-01-1995
US 5522899	A	04-06-1996	US 5609635 A	11-03-1997
		•	US 5776199 A	07-07-1998
	•		AT 119015 T	15-03-1995
			AU 3965489 A	23-01-1990
			CA 1333209 A	29-11-1994
			CA 1337842 A	02-01-1996
			DE 68921482 D	06-04-1995
			DE 68921482 T	20-07-1995
		•	EP 0425542 A	08-05-1991
			EP 0734702 A	02-10-1996
			EP 0637439 A	08-02-1995
,			JP 3505416 T	28-11-1991
			WO 9000037 A	11-01-1990
EP 260044	Α	16-03-1988	JP 63145650 A	17-06-1988
			US 4863476 A	05-09-1989
WO 9706753	Α	27-02-1997	DE 19529605 A	13-02-1997
			DE 19549426 A	20-02-1997
			EP 0844856 A	03-06-1998
SU 1424826	, <b>A</b>	23-09-1988	NONE	
US 5653763	Α	05-08-1997	US 5714145 A	03-02-1998
US 5665122	Α	09-09-1997	NONE	

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